

2005 No. 641

NATIONAL HEALTH SERVICE, ENGLAND

**The National Health Service (Pharmaceutical Services)
Regulations 2005**

Made - - - - *10th March 2005*
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Coming into force - - *1st April 2005*

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The Secretary of State for Health, in exercise of the powers conferred upon him by sections 41, 42, 43, 43ZA, 49F, 49I, 49N, 49O, 49P, 49Q and 126(4) of the National Health Service Act 1977(a) hereby makes the following Regulations:—

(a) 1977 c.49; section 41 was substituted by the Health and Social Care Act 2001 (c.15) (“the 2001 Act”), section 42(1), and amended by the National Health Service Reform and Healthcare Professions Act 2002 (c.17) (“the 2002 Act”), Schedule 2, Part 1, paragraphs 1 and 13; and by the Health Professions Order 2001 (Consequential Amendments) Order 2003 (S.I. 2003/1590) article 3, Schedule, Part 1, paragraph 3 and the Health Act 1999 (Consequential Amendments) (Nursing and Midwifery) Order 2004 (S.I. 2004/1771) article 8. Section 42 was substituted by the National Health Service (Amendment) Act 1986 (c.66), section 3(1); extended by the Health and Medicines Act 1988 (c.49), section 17; and amended by S.I. 1987/2202, article 4; by the National Health Service and Community Care Act 1990 (c.19) (“the 1990 Act”), section 12(3); by the Health Authorities Act 1995 (c.17) (“the 1995 Act”), Schedule 1, paragraph 30; by the Pharmacists (Fitness to Practice) Act 1997 (c.19), Schedule, paragraph 6; by the 2001 Act, sections 20(6), 43(2), (3) and (4) and by Schedule 6 Part

PART 1

General

Citation, commencement and extent

1.—(1) These Regulations may be cited as the National Health Service (Pharmaceutical Services) Regulations 2005 and shall come into force on 1st April 2005.

(2) Subject to paragraph (3), these Regulations shall apply in relation to England only(a).

(3) The amendments and revocations of enactments made by regulation 75 and Schedules 5 and 6 have, subject to paragraph (4), no application to Wales but, subject to that, the extent of those provisions is the same as that of the enactment amended or revoked.

(4) The amendments made by regulation 75 and paragraph 4 of Schedule 5 apply to Wales.

Interpretation

2.—(1) In these Regulations—

“the Act” means the National Health Service Act 1977;

“the 1992 Regulations” means the National Health Service (Pharmaceutical Services) Regulations 1992(b), as in force on 31st March 2005;

“the 1997 Act” means the National Health Service (Primary Care) Act 1997(c);

“the 2001 Act” means the Health and Social Care Act 2001(d);

“the 2002 Act” means the National Health Service Reform and Health Care Professions Act 2002(e);

“Abolition of the Tribunal Regulations” means the Abolition of the National Health Service Tribunal (Consequential Provisions) Regulations 2001(f);

“Abolition of the Tribunal (Wales) Regulations” means the Abolition of the National Health Service Tribunal (Consequential Provisions) Regulations 2002(g);

“advanced electronic signature” means an electronic signature which is—

- (a) uniquely linked to the signatory;
- (b) capable of identifying the signatory;
- (c) created using means that the signatory can maintain under his sole control; and
- (d) linked to the data to which it relates in such a manner that any subsequent change of data is detectable;

“APMS” means primary medical services provided in accordance with an APMS contract;

“APMS contract” means an arrangement to provide primary medical services made under section 16CC(2)(b) (primary medical services)(a) of the Act;

1997 Act”), section 29(1) and Schedule 2, paragraphs 3 and 14; by the 1990 Act, Schedule 9, paragraph 18(2); by the 2001 Act, sections 20(7), 42(2) and 43(5); and by the 2002 Act, Schedule 2, paragraph 17. Section 43ZA was inserted by the 2001 Act, section 21, and amended by the 2002 Act, section 2(5) and Schedule 2, Part 1, paragraphs 1 and 18, and by the Health and Social Care (Community Health and Standards) Act 2003 (c.43) (“the 2003 Act”), Schedule 14, Part 4. Sections 49F, 49I, 49N, 49O and 49Q were inserted by the 2001 Act, section 25 and amended by the 2002 Act, Schedule 2, paragraphs 1, 21, 23, 24, 25, 26, 27 and 28. Section 126(4) was amended by the Health Act 1999 (“the 1999 Act”), section 65(1), Schedule 4, paragraphs 3 and 37. See section 128(1) of the National Health Service Act 1977 as amended by the 1990 Act, section 26(2)(g) and (i), for the definitions of “prescribed” and “regulations”.

(a) As regards Wales, the functions of the Secretary of State under sections 41, 42, 43, 43ZA, 49F, 49I, 49N, 49O, 49P, 49Q and 126(4) of the 1977 Act were transferred to the National Assembly for Wales under S.I. 1999/672, article 2 and Schedule 1, as amended by the 1999 Act, section 66(5) and as read with section 40(1) of the 2002 Act.

(b) S.I. 1992/662 as amended by 1993/2451, 1994/2402, 1995/644, 1996/698, 1998/681, 1998/2224, 1999/696, 1999/2563, 2000/121, 2000/593, 2001/2888, 2002/551, 2002/888, 2002/2016, 2002/2469, 2002/2861, 2003/699, 2003/1084, 2004/922, and 2005/28.

(c) 1997 c.46.

(d) 2001 c.15.

(e) 2002 c.17.

(f) S.I. 2001/3744.

(g) S.I. 2002/1920.

“APMS contractor” means a party to an APMS contract other than a Primary Care Trust;

“appliance” means an appliance which is included in a list for the time being approved by the Secretary of State for the purposes of section 41 (arrangements for pharmaceutical services) of the Act;

“appropriate non-proprietary name” means a non-proprietary name which is not mentioned in Schedule 1 (drugs, medicines and other substances not to be ordered under a general medical services contract) to the Prescription of Drugs Regulations or, except where the conditions in paragraph 42(2) of Schedule 6 to the GMS Regulations are satisfied, in Schedule 2 (drugs, medicines and other substances that may be ordered only in certain circumstances) to the Prescription of Drugs Regulations;

“associated batch issue” means, in relation to a non-electronic repeatable prescription, one of the batch issues relating to that prescription and containing the same date as that prescription;

“bank holiday” means any day that is specified or proclaimed as a bank holiday in England pursuant to section 1 of the Banking and Financial Dealings Act 1971**(b)**;

“batch issue” means a form provided by a Primary Care Trust and issued by a repeatable prescriber at the same time as a non-electronic repeatable prescription to enable a chemist to receive payment for the provision of repeat dispensing services which is in the format specified in Part 2 of Schedule 1 to the GMS Regulations, and which—

- (a) is generated by a computer and not signed by a repeatable prescriber;
- (b) relates to a particular non-electronic repeatable prescription and contains the same date as that prescription;
- (c) is issued as one of a sequence of forms, the number of which is equal to the number of occasions on which the drugs or appliances ordered on the non-electronic repeatable prescription may be provided; and
- (d) specifies a number denoting its place in the sequence referred to in sub-paragraph (c);

“Charges Regulations” means the National Health Service (Charges for Drugs and Appliances) Regulations 2000**(c)**;

“chemical reagent” means a chemical reagent included in a list for the time being approved by the Secretary of State for the purposes of section 41 of the Act;

“chemist”, except in the expression “LPS chemist”, means—

- (a) a registered pharmacist;
- (b) a person lawfully conducting a retail pharmacy business in accordance with section 69 of the Medicines Act 1968**(d)**; or
- (c) a supplier of appliances,

who is included in the list of a Primary Care Trust under section 42 (regulations as to pharmaceutical services) of the Act, and includes a person suspended from such a list;

“child” means a person who has not attained the age of 16 years;

“Community Health Council” means a body of that name established in accordance with section 20 of the Act;

“conditional inclusion” means inclusion in a pharmaceutical list (or the grant of preliminary consent to be included in a pharmaceutical list) subject to conditions imposed under regulation 21, 30, 42 or 43 and “conditionally include” shall be construed accordingly;

“contingent removal” means removal from a pharmaceutical list contingently, within the meaning of section 49G (contingent removal)**(e)** of the Act, and “contingently remove” shall be construed accordingly;

(a) Section 16CC was inserted by the 2003 Act, section 174.

(b) 1971 c.80.

(c) S.I. 2000/620, as amended by S.I. 2000/2393, 2000/3189, 2001/746, 2001/2887, 2002/258, 2002/548, 2002/2352, 2003/699, 2003/1084, 2004/663, 2004/696, 2004/865 and 2004/1771.

(d) 1968 c.67. Section 69 was amended by the Statute Law (Repeals) Act 1993 (c.50).

(e) Section 49G was inserted by section 25 of the 2001 Act and amended by the 2002 Act, Schedule 2 paragraph 21.

“controlled locality” means an area which the Primary Care Trust, or on appeal, the Secretary of State, has determined is rural in character in accordance with regulation 31 or, as the case may be, regulation 32;

“dentist” means a dental practitioner;

“directed services” means additional pharmaceutical services provided in accordance with a direction under section 41A(a) (arrangements for providing additional pharmaceutical services) of the Act;

“director” means—

(a) a director of a body corporate; or

(b) a member of the body of persons controlling a body corporate (whether or not a limited liability partnership);

“dispensing contractor” means a chemist, doctor, GMS contractor or PMS contractor whom a patient wishes to dispense his electronic prescriptions;

“dispensing doctor” means a doctor who provides pharmaceutical services under arrangements with a Primary Care Trust under Part 5;

“dispensing doctor list” shall be construed in accordance with regulation 68;

“distance selling chemist” means a chemist who provides pharmaceutical services from distance selling premises;

“distance selling premises” has the meaning given to it in regulation 13(1)(d);

“doctor” means a medical practitioner;

“drugs” includes medicines;

“Drug Tariff” has the meaning given to it in regulation 56;

“electronic communication” has the same meaning as in section 15 of the Electronic Communications Act 2000(b);

“electronic prescription” means an electronic prescription form or an electronic repeatable prescription;

“electronic prescription form” means a prescription which falls within paragraph (b) of the definition of “prescription form”;

“electronic repeatable prescription” means a prescription which falls within paragraph (a)(ii) of the definition of “repeatable prescription”;

“employment” means any employment whether paid or unpaid and whether under a contract for services or a contract of service, and “employed” and “employer” shall be construed accordingly;

“equivalent body” means a Local Health Board in Wales, a Health Board or an NHS trust in Scotland, a Health and Social Services Board in Northern Ireland, (in relation to any time prior to 1st October 2002) a Health Authority in England or (in relation to any time prior to 1st April 2003) a Health Authority in Wales;

“equivalent lists” means lists kept by an equivalent body;

“essential services” has the meaning given to it in paragraph 3 of Schedule 1 (essential services);

“ETP list” means the list prepared, maintained and published by a Primary Care Trust pursuant to regulation 71.

“ETP service” means the electronic prescription service which forms part of the NHS Care Record Service;

(a) Section 41A was inserted into the Act by the 1997 Act, section 27(1) and was amended by the 2001 Act, section 43(1) and the 2002 Act, Schedule 2, paragraph 14.

(b) 2000 c.7.

“FHSAA” means the Family Health Services Appeal Authority constituted under section 49S of the Act(a);

“finally granted” and “final grant” (except in regulations 40 and 41) have the meaning given to them in regulation 39(14) and “finally refused” and “finally determined” shall be construed accordingly;

“fraud case” means a case where a person satisfies the second condition for removal from the pharmaceutical list, set out in section 49F(3) (disqualification of practitioners) of the Act, or by virtue of section 49H (fraud and unsuitability cases: supplementary)(b) of the Act is treated as doing so;

“GMS contract” means a general medical services contract(c);

“GMS contractor” means a party to a GMS contract other than a Primary Care Trust;

“the GMS Regulations” means the National Health Service (General Medical Services Contracts) Regulations 2004(d);

“Health and Social Services Board” means a Health and Social Services Board established under the Health and Personal Social Services (Northern Ireland) Order 1972(e);

“Health Board” means a Health Board established under section 2 of the National Health Service (Scotland) Act 1978(f);

“health care professional” means a person who is a member of a profession regulated by a body mentioned in section 25(3) of the 2002 Act;

“independent nurse prescriber” means a person—

- (a) who is registered in the Nursing and Midwifery Register; and
- (b) in respect of whom an annotation signifying that he is qualified to order drugs and appliances from—
 - (i) the Nurse Prescribers’ Formulary for District Nurses and Health Visitors in Part XVIIIB(i) of the Drug Tariff, or
 - (ii) the Nurse Prescribers’ Extended Formulary in Part XVIIIB(ii) of the Drug Tariff,is also recorded in that register;

“joint discipline committee” shall have the same meaning as in the National Health Service (Service Committees and Tribunal) Regulations 1992(g);

“licensing or regulatory body” means a body that licenses or regulates any profession of which the person is or has been a member, and includes any body which licenses or regulates any such profession in a country other than the United Kingdom;

“list”, unless the context otherwise requires, means—

- (a) a list referred to in section 49N(1)(a) to (c)(national disqualification) of the Act(h);
- (b) a list of persons undertaking to provide general medical services prepared in accordance with regulations made under section 29 (arrangements and regulations for general medical services)(i) of the Act, as the list existed on or before 31st March 2004;
- (c) a list of persons approved by a Primary Care Trust for the purpose of assisting in the provision of general medical services prepared in accordance with regulations made

(a) Section 49S was inserted into the Act by section 27(1) of the 2001 Act.

(b) Sections 49F and 49H were inserted by section 25 of the 2001 Act. Section 49F was amended by the 2002 Act, Schedule 2, paragraph 21(a) and by the 2003 Act, Schedule 14, Part 4. Section 49H was amended by the 2003 Act, Schedule 14, Part 4.

(c) See section 28Q of the Act.

(d) S.I. 2004/291, as amended by S.I. 2004/906, 2004/2694 and 2005/28.

(e) S.I. 1972/1265 (N.I. 14).

(f) 1978 c.29.

(g) S.I. 1992/664. Relevant amendments were made by S.I. 1996/703.

(h) Section 49N was inserted by section 25 of the 2001 Act and amended by the 2002 Act, Schedule 2, paragraph 25 and the 2003 Act, Schedule 11, paragraph 24(a).

(i) Section 29 was repealed by section 175(2) of the 2003 Act.

under section 43D(1) (supplementary lists)(a) of the Act as the list existed on or before 31st March 2004; or

- (d) a services list referred to in section 8ZA(1)(a) (lists of persons who may perform personal medical services or personal dental services)(b) of the 1997 Act as the list existed on or before 31st March 2004;

“listed premises” means premises in relation to which premises approval has been granted and has effect and from which a doctor may dispense, being premises specified in relation to the doctor in the dispensing doctors list pursuant to regulation 68(4);

“Local Dental Committee” means a committee recognised under section 44 (Local Optical Committees and Local Pharmaceutical Committees)(c) of the Act as being representative of persons providing general dental services or personal dental services in an area; and in this definition, “personal dental services” has the meaning assigned to it in section 1 (pilot schemes) of the 1997 Act;

“Local Medical Committee” means a committee recognised under section 45A (Local Medical Committees) of the Act(d);

“Local Pharmaceutical Committee” means a committee recognised under section 44 of the Act as being representative of persons providing pharmaceutical services or local pharmaceutical services in a locality;

“local pharmaceutical services” has the meaning given in regulation 2 of the National Health Service (Local Pharmaceutical Services and Pharmaceutical Services) Regulations 2002(e);

“LPS chemist” means—

- (a) a registered pharmacist,
(b) a person lawfully conducting a retail pharmacy business in accordance with section 69 of the Medicines Act 1968, or
(c) a supplier of appliances,

who provides local pharmaceutical services under a pharmacy pilot scheme;

“medical performers list” means a list of doctors prepared and published pursuant to regulation 3(1) (performers lists) of the National Health Service (Performers Lists) Regulations 2004(f);

“national disqualification” means—

- (a) a decision made by the FHSAA under section 49N (national disqualification) of the Act in relation to a person who has been removed from a pharmaceutical list;
(b) a decision under provisions in force in Scotland or Northern Ireland corresponding to section 49N of the Act; or
(c) a decision by the Tribunal which is treated as a national disqualification by the FHSAA by virtue of regulation 4 (national disqualification decisions made before the relevant date) or 6(4)(b) (other cases under the 1977 Act not disposed of by the relevant date) of the Abolition of the Tribunal Regulations or regulation 4 (national disqualification decisions made before the relevant date) or 6(4)(b) (other cases under the 1977 Act not disposed of by the relevant date) of the Abolition of the Tribunal (Wales) Regulations;

“National Health Service Counter Fraud and Security Management Service” means the Special Health Authority of that name with responsibility for policy and operational matters

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- (a) Section 43D was inserted by section 24 of the 2001 Act, and amended by the 2002 Act, Schedule 2, paragraph 20 and the 2003 Act, Schedule 11, paragraph 20(a) and Schedule 14, Part 4 in relation to personal medical services only.
(b) Section 8ZA was inserted by the 2001 Act, section 26(2) and amended by the 2002 Act, Schedule 3, paragraph 3.
(c) Section 44 was amended by the Health and Social Security Act 1984 (c. 48), Schedule 1, paragraph 32(b) and Schedule 8, Part 1, the 1990 Act, section 12(4), the 1995 Act, Schedule 1, Part 1, paragraph 32, the 1999 Act, section 11(1) to (4) and Schedule 5, the 2001 Act, Schedule 5, paragraph 5(7) and Schedule 6, Part 1, the 2002 Act, section 5 and Schedule 9 and the 2003 Act, Schedule 11, paragraph 21 and Schedule 14, Part 4.
(d) Section 45A was inserted into the Act by the 2003 Act, Schedule 11, paragraph 23.
(e) S.I. 2002/888.
(f) S.I. 2004/585.

relating to the prevention, detection and investigation of fraud or corruption and the management of security in the National Health Service(a);

“NHS Care Record” means the records relating to an individual patient held by the NHS Care Record Service;

“NHS Care Record Service” means the information technology systems procured by the Department of Health and used by the health service to hold medical records relating to patients;

“NHS services” means services provided as part of the health service;

“nominated dispensing contractor” means a chemist, doctor, GMS contractor or PMS contractor whom a patient has nominated in his NHS Care Record to dispense his electronic prescriptions;

“non-electronic prescription form” means a prescription form which falls within paragraph (a) of the definition of “prescription form”;

“non-electronic repeatable prescription” means a prescription which falls within paragraph (a)(i) of the definition of repeatable prescription;

“non-proprietary name”, in relation to a drug, means—

(a) where the drug is described in a monograph in the current edition (as defined in section 103(5) (construction of references to specified publications)(b) of the Medicines Act 1968), as in force at the time of the supply of the drug, of the European Pharmacopoeia, the British Pharmacopoeia, the British Pharmaceutical Codex, the British National Formulary, the International Pharmacopoeia, the Cumulative List of Recommended International Non-proprietary Names or the Dental Practitioners’ Formulary, any name, or abbreviation of the name, at the head of that monograph or, where the name consists of two or more words, any name derived from a suitable inversion of such words which is permitted by that publication; or

(b) where the drug is not so described but has an approved name, being the name which appears in the current edition (as defined in section 103(5) of the Medicines Act 1968) of the list of names prepared and published under section 100 (lists of names) of that Act, as in force at the time of the supply of the drug, its approved name;

“notice” means a notice in writing (including electronic) and “notify” shall be construed accordingly;

“Nursing and Midwifery Register” means the register maintained by the Nursing and Midwifery Council under article 5 of the Nursing and Midwifery Order 2001(c);

“originating events” means the events that gave rise to the conviction, investigation, proceedings, suspension, refusal to admit, conditional inclusion, removal or contingent removal that took place;

“outstanding application” except where the context otherwise requires has the meaning given to it in regulation 62(5);

“outline consent” has the meaning given to it in regulation 61(1)(a);

“patient” in relation to—

(a) a GMS contract has the same meaning as in regulation 2 of the GMS Regulations (interpretation);

(b) a PMS agreement has the same meaning as in regulation 2 of the PMS Regulations (interpretation); and

(a) The National Health Service Counter Fraud and Security Management Service was established by S.I. 2002/3039, and replaces the National Health Service Counter Fraud Service. They may be contacted by writing to them at Weston house, 246 High Holborn, London WC1V 7EX, or e-mailing them on generalenquiries@cfms.nhs.uk, or by telephone on 020 7895 4500 or specifically in relation to fraud and corruption on 08702-400-100.

(b) 1968 c.67. Section 103(5) was amended by the Health and Medicines Act 1988 (c.49), section 22(6) and modified by S.I. 1994/3144.

(c) S.I. 2002/253.

(c) an arrangement made under section 16CC(2)(b) of the Act or a PCTMS practice means any person to whom primary medical services are or are to be provided under those arrangements or by that practice;

“patient list” means a list of patients kept by a Primary Care Trust—

(a) in respect of a GMS contractor, in accordance with paragraph 14 (list of patients) of Schedule 6 to the GMS Regulations;

(b) in respect of a PMS contractor, in accordance with paragraph 13 (list of patients) of Schedule 5 to the PMS Regulations; or

(c) in respect of an APMS contractor or PCTMS practice, in accordance with directions given by the Secretary of State under section 17 of the Act in respect of an APMS contract or a PCTMS practice(a);

“Patients’ Forum” means a body established under section 15(1) (establishment of Patients’ forums) of the 2002 Act;

“PCTMS” means primary medical services provided by a Primary Care Trust under section 16CC(2)(a) of the Act;

“PCTMS practice” means a practice established by a Primary Care Trust to provide PCTMS;

“pharmaceutical discipline committee” has the same meaning as in the National Health Service (Service Committees and Tribunal) Regulations 1992(b);

“pharmaceutical list” shall be construed in accordance with regulation 4;

“pharmaceutical services” means pharmaceutical services other than directed services;

“pharmacist” means, except where the context otherwise requires—

(a) a registered pharmacist; or

(b) a person lawfully conducting a retail pharmacy business in accordance with section 69 of the Medicines Act 1968,

whose name is included in the list of a Primary Care Trust under section 42 (regulations as to pharmaceutical services) of the Act, but does not include a supplier of appliances only,;

“pharmacy” means any premises where drugs are provided by a pharmacist—

(a) as part of pharmaceutical services under section 41 (arrangements for pharmaceutical services) of the Act; or

(b) in accordance with a pharmacy pilot scheme—

(i) where the range of local pharmaceutical services provided under that scheme is the same or comparable to the range of pharmaceutical services provided by a pharmacy falling within paragraph (a) of this definition, and

(ii) where the local pharmaceutical services provided under that scheme are provided at the same or similar hours as pharmaceutical services provided by a pharmacy falling within paragraph (a) of this definition;

“pharmacy pilot scheme” has the same meaning as the term “pilot scheme” in section 28(2) (pilot schemes)(c) of the 2001 Act;

“PMS agreement” means an agreement made under section 28C (personal medical or dental services) of the Act(d);

(a) The current Directions are the APMS (No.2) Directions 2004, made on 3rd November 2004 and the PCTMS (No.2) Directions made on 3rd November 2004. A copy of the Directions is available on the Department of Health website at www.dh.gov.uk.

(b) S.I. 1992/664. A relevant amendment was made by S.I. 1996/703.

(c) Section 28 has been amended by the 2002 Act, Schedule 2, paragraph 73 and the 2003 Act Schedule 4, paragraph 11 and Schedule 11 paragraph 71.

(d) Section 28C was inserted by the 1997 Act, section 21(1) and amended by the 1999 Act, Schedule 4, paragraphs 4 and 5; by the 2001 Act, Schedule 5, Part 1, paragraph 11; by the 2002 Act, Schedule 3, Part 1, paragraphs 1 and 7 and by the 2003 Act, section 184, Schedule 11, paragraph 14 and Schedule 14 Part 4.

“PMS contractor” means a party to a PMS agreement, other than a Primary Care Trust or a Strategic Health Authority;

“the PMS Regulations” means the National Health Service (Personal Medical Services Agreements) Regulations 2004(a);

“practice amalgamation” has the meaning given to it in regulation 66(1);

“practice premises”, in relation to a provider of primary medical services, means the address specified in the contract (in the case of a GMS, PMS or APMS contractor) or practice statement (in the case of a PCTMS practice) as one at which services are to be provided under the contract or practice statement;

“preliminary consent” has the meaning given to it in regulation 40;

“premises approval” has the meaning given to it in regulation 61(1)(b) and includes temporary premises approval granted under regulation 65(9) or 66(4) and residual premises approval under regulation 66(9);

“prescriber” means a doctor, dentist, independent nurse prescriber or a supplementary prescriber;

“prescription form” means—

- (a) a form provided by a Health Board, a Health and Social Services Board, a Local Health Board, a Primary Care Trust, an NHS Trust or NHS Foundation Trust, and issued by a prescriber; or
- (b) data that are created in an electronic form, signed with a prescriber’s advanced electronic signature and transmitted as an electronic communication to a nominated dispensing contractor by the ETP service,

to enable a person to obtain pharmaceutical services or local pharmaceutical services, and does not include a repeatable prescription;

“the Prescription of Drugs Regulations” means the National Health Service (General Medical Services Contracts) (Prescription of Drugs etc) Regulations 2004(b);

“primary carer” means, in relation to an adult, the adult or organisation primarily caring for him;

“professional conduct” includes matters relating both to professional conduct and professional performance;

“professional registration number” means the number against the pharmacist’s name in the register maintained by the Royal Pharmaceutical Society of Great Britain and in the case of a person who is not a pharmacist, means the number against that person’s name in the register of any body that licenses or regulates any profession of which he is a member;

“provisional date” shall be interpreted in accordance with regulation 62(6) to (8);

“provider of primary medical services” means a GMS contractor, PMS contractor, APMS contractor or a PCTMS practice;

“relevant APMS contractor”, in relation to any doctor, means the APMS contractor, where the doctor is an APMS contractor, or where he is not, the APMS contractor by whom he is employed or engaged;

“relevant GMS contractor”, in relation to any doctor, means the GMS contractor, where the doctor is a GMS contractor or, where he is not, the GMS contractor by whom the doctor is employed or engaged;

“relevant patient list” means, in relation to a doctor who is (or is a legal and beneficial shareholder in a company which is) a GMS contractor, PMS contractor or APMS contractor, the patient list for that contractor or, where he is not a contractor, means the patient list for the GMS contractor, PMS contractor or APMS contractor by whom he is employed or engaged or for the PCTMS practice within which the doctor provides primary medical services;

(a) S.I. 2004/627, as amended by S.I. 2004/906, 2004/2694 and 2005/28.

(b) S.I. 2004/629, as amended by S.I. 2004/3215.

“relevant PCTMS practice”, in relation to any doctor, means the PCTMS practice within which he provides primary medical services;

“relevant PMS contractor”, in relation to any doctor, means the PMS contractor, where the doctor is a PMS contractor or, where he is not, the PMS contractor by whom the doctor is employed or engaged;

“relevant register” means—

- (a) in relation to a nurse or midwife, the Nursing and Midwifery Register; and
- (b) in relation to a pharmacist, the register maintained in pursuance of section 2(1) of the Pharmacy Act 1954^(a) (the registers and registration) or the register maintained in pursuance of Articles 6 (the registers) and 9 (the registrar) of the Pharmacy (Northern Ireland) Order 1976^(b);

“Remission of Charges Regulations” means the National Health Service (Travel Expenses and Remission of Charges) Regulations 2003^(c);

“repeat dispensing services” means pharmaceutical services which involve the provision of drugs or appliances by a chemist in accordance with a repeatable prescription;

“repeatable prescriber” means a person who is—

- (a) a GMS contractor who provides repeatable prescribing services under the terms of its contract which give effect to paragraph 40 (repeatable prescribing services) of Schedule 6 to the GMS Regulations;
- (b) a PMS contractor who provides repeatable prescribing services under the terms of its agreement which give effect to paragraph 39 (repeatable prescribing services) of Schedule 5 to the PMS Regulations;
- (c) an APMS contractor who provides repeatable prescribing services under the terms of its agreement which give effect to a provision in directions made by the Secretary of State under section 17 of the Act in relation to APMS contracts which is the equivalent provision to paragraph 39 of Schedule 5 to the PMS Regulations; or
- (d) employed or engaged by—
 - (i) a GMS contractor who provides repeatable prescribing services under the terms of a contract which give effect to paragraph 40 of Schedule 6 to the GMS Regulations,
 - (ii) a PMS contractor who provides repeatable prescribing services under the terms of an agreement which give effect to paragraph 39 of Schedule 5 to the PMS Regulations,
 - (iii) an APMS contractor who provides repeatable prescribing services under the terms of an agreement which give effect to a provision in directions made by the Secretary of State under section 17 of the Act in relation to APMS contracts which is the equivalent provision to paragraph 39 of Schedule 5 to the PMS Regulations, or
 - (iv) a Primary Care Trust for the purposes of providing primary medical services within a PCTMS practice which provides repeatable prescribing services in accordance with a provision in directions made by the Secretary of State under section 17 of the Act in relation to PCTMS which is the equivalent provision to paragraph 39 of Schedule 5 to the PMS Regulations;

“repeatable prescription” means a prescription which—

- (a) either—
 - (i) is contained in a form provided by a Primary Care Trust and issued by a repeatable prescriber which is in the format specified in Part 1 of Schedule 1 (repeat dispensing forms) to the GMS Regulations, and which is generated by a computer and signed in ink by a repeatable prescriber, or

(a) 1954 c.61.

(b) S.I. 1976/1212 (N.I.22).

(c) S.I. 2003/2382, amended by S.I. 2004/663 and 2004/936.

- (ii) consists of data that are created in an electronic form, signed with a repeatable prescriber's advanced electronic signature and transmitted as an electronic communication to a nominated dispensing contractor by the ETP service;
- (b) is issued or created to enable a person to obtain pharmaceutical services or local pharmaceutical services; and
- (c) indicates that the drugs or appliances ordered on that prescription may be provided more than once, and specifies the number of occasions on which they may be provided;

“reserved location” has the meaning given to it in regulation 35(2);

“restricted availability appliance” means an appliance which is approved for particular categories of persons or particular purposes only;

“Scheduled drug” means a drug or other substance specified in Schedule 1 to the Prescription of Drugs Regulations or, except where the conditions in paragraph 42(2) of Schedule 6 to the GMS Regulations are satisfied, Schedule 2 to the Prescription of Drugs Regulations;

“superintendent” has the same meaning as it has in section 71 (bodies corporate)(a) of the Medicines Act 1968;

“supplementary prescriber” means a person—

- (a) whose name is registered in—
 - (i) the Nursing and Midwifery Register,
 - (ii) the Register of Pharmaceutical Chemists maintained in pursuance of section 2(1) (the registers and registration) of the Pharmacy Act 1954,
 - (iii) the register maintained in pursuance of Articles 6 and 9 of the Pharmacy (Northern Ireland) Order 1976. or
 - (iv) the part of the register maintained by the Health Professions Council in pursuance of article 5 of the Health Professions Order 2001(b) relating to—
 - (aa) chiropodists and podiatrists,
 - (bb) physiotherapists, or
 - (cc) radiographers: diagnostic or therapeutic; and
- (b) against whose name is recorded in the relevant register an annotation signifying that he is qualified to order drugs and appliances as a supplementary prescriber;

“suspended” means—

- (a) suspended by a Primary Care Trust or equivalent body under sections 49I (suspension) or 49J (suspension pending appeal)(c) of the Act, regulations made under section 28DA (lists of persons who may perform personal medical services or personal dental services)(d) or 43D(supplementary lists) of the Act, or under section 8ZA (lists of persons who may perform personal medical services or personal dental services) of the 1997 Act; or
- (b) in relation to Scotland or Northern Ireland, suspended under provisions in force corresponding to those in or made under sections 28DA, 43D, 49I or 49J of the Act or under section 8ZA of the 1997 Act,

and shall be treated as including a case where a person is treated as suspended by a Primary Care Trust or, prior to 1st October 2002, by a Health Authority by virtue of regulation 6(2) of the Abolition of the Tribunal Regulations, or, in Wales, by a Local Health Board, or prior to 1st April 2003, by a Health Authority by virtue of regulation 6(2) of the Abolition of the Tribunal (Wales) Regulations, and “suspends” and “suspension” shall be construed accordingly;

(a) 1967 c.67. Section 72 was amended by S.I. 1987/2202.

(b) S.I. 2002/254.

(c) Section 49J was inserted by the 2001 Act, section 25 and amended by the 2002 Act, Schedule 2, paragraph 22.

(d) Section 28DA was inserted into the Act by the 2001 Act, section 26(1), and repealed by the 2003 Act, Schedule 14, Part 4, in relation to personal medical services.

“temporary chemist” means a chemist whose application has been granted under regulation 54 and who is included in a pharmaceutical list pursuant to that regulation;

“terms of service” shall be construed in accordance with regulation 3; and

“Tribunal” means the Tribunal constituted under section 46 of the Act(a) for England and Wales, and which, except for prescribed cases, had effect in relation to England only until 14th December 2001, and in relation to Wales only until 26th August 2002(b).

(2) In these Regulations—

(a) the term “pharmaceutical services”, in relation to a doctor, means those services referred to in regulation 60; and

(b) the term “dispensing services”, in relation to a doctor or to a GMS contractor or PMS contractor, means any corresponding service provided, not as pharmaceutical services, but under the terms of a GMS contract which give effect to paragraphs 47 to 51 of Schedule 6 to the GMS Regulations or under the terms of a PMS agreement which give effect to paragraph 45 to 51 of Schedule 5 to the PMS Regulations.

(3) Except where expressly provided to the contrary, any document which is required or authorised to be given or sent to a person or body under these Regulations may be given or sent by delivering it to the person or, in the case of a body, to the secretary or general manager of that body, or by sending it in a pre-paid letter addressed to that person or, in the case of a body, to the secretary or general manager of that body at his usual or last known address, and delivering it includes sending it electronically to an electronic address which that person has notified for the purpose.

(4) For as long as there are in existence—

(a) contracts entered into under article 13 (entitlement to a contract under section 176(3) of the Act) of the General Medical Services Transitional and Consequential Provisions Order 2004(c) (“default contracts”), in respect of such contracts any reference to a GMS contract shall be read as including a reference to a contract entered into under that article, and any reference to a term of a GMS contract shall be read as including a reference to the equivalent term in the default contract; and

(b) transitional agreements as defined in article 1(4) of the General Medical Services and Personal Medical Services Transitional and Consequential Provisions Order 2004, any reference in these Regulations to a PMS agreement shall be read as including a reference to any equivalent term in the transitional agreement.

Terms of service

3. The arrangements for the provision of pharmaceutical services which it is the duty of a Primary Care Trust to make under sections 41 to 43 of the Act, and to administer under section 15(1) of the Act, shall incorporate—

(a) in the case of arrangements with a pharmacist, the terms of service in Schedule 1;

(b) in the case of arrangements with a doctor who provides pharmaceutical services, the terms of Service in Schedule 2; and

(c) in the case of arrangements with a supplier of appliances, the terms of service in Schedule 3.

(a) Section 46 was substituted by the 1999 Act, and repealed by the 2001 Act, section 16.

(b) See S.I. 2001/3738, article 2(5) and (6)(b), which sets out the prescribed cases for England, and S.I. 2002/1919, article 2(2) and (3)(b), which sets out the prescribed cases for Wales.

(c) S.I. 2004/433.

PART 2

Pharmaceutical Lists and Applications for Admission to a Pharmaceutical List

Preparation of lists

4.—(1) A Primary Care Trust shall prepare and publish lists, to be called pharmaceutical lists, of the persons, other than doctors and dentists—

- (a) whose applications to be included in a pharmaceutical list have been granted by the Primary Care Trust, subject to and in accordance with the provisions of these Regulations, and who accordingly undertake to provide pharmaceutical services from premises in the Primary Care Trust's area, in particular, by way of the provision of drugs; and
- (b) whose applications to be included in a pharmaceutical list have been granted by the Primary Care Trust, subject to and in accordance with the provisions of these Regulations, and who accordingly undertake to provide pharmaceutical services from premises in the Primary Care Trust's area by way of the provision of appliances.

(2) Each such list shall contain—

- (a) the addresses of premises in the Primary Care Trust's area from which those services are provided;
- (b) the days on which and times at which pharmaceutical services are provided at that address (including times at which those services are provided when the person is not obliged to do so); and
- (c) in the case of a list referred to in paragraph (1)(a), shall indicate whether or not the chemist has undertaken to provide directed services, and if he has, which services.

(3) The pharmaceutical lists shall be available for public inspection.

Applications for inclusion in or amendment to a pharmaceutical list

5.—(1) Subject to paragraph (4), a person, other than a doctor or dentist—

- (a) who wishes to be included in a pharmaceutical list for the provision of pharmaceutical services from premises in a Primary Care Trust's area;
- (b) who is already included in a pharmaceutical list but wishes—
 - (i) to open, within a Primary Care Trust's area, additional premises from which to provide the same or different pharmaceutical services,
 - (ii) to change the premises from which he provides pharmaceutical services to other premises within that area from which he wishes to provide the same or different pharmaceutical services, or
 - (iii) to provide from his existing premises in that area pharmaceutical services other than those already listed in relation to him; or
- (c) who is already included in a pharmaceutical list of a neighbouring Primary Care Trust but wishes to change the premises within the neighbourhood from which he provides pharmaceutical services to other premises in the area of the Primary Care Trust to which he makes an application under this Regulation and—
 - (i) the change is a minor relocation, and
 - (ii) the same pharmaceutical services will be provided,

shall apply, in accordance with this regulation, to the Primary Care Trust, providing the information set out in Part 1 of Schedule 4.

(2) A person applying in accordance with paragraph (1)(a) shall provide the information and undertakings specified in Part 3 of Schedule 4.

(3) A person who wishes to be included in a Primary Care Trust's pharmaceutical list—

- (a) pursuant to a determination made by the Secretary of State under regulation 4 of the National Health Service (Local Pharmaceutical Services and Pharmaceutical Services) (No. 2) Regulations 2002(a); or
- (b) as a temporary chemist,

shall apply under regulation 10 or 54 (as the case may be), and not under this regulation.

(4) In this Part and in regulation 54 and Schedule 4 and unless the context otherwise requires, “applicant” and “application” shall be construed accordingly.

(5) Where an application has been granted under regulation 6 or 7, no further application may be granted under regulation 6 or 7 in relation to those new premises for a period of 12 months beginning with the date on which the applicant commenced the provision of pharmaceutical services from the new premises unless the Primary Care Trust for good cause allows him to make an application before the end of that period.

Applications involving a minor relocation within a Primary Care Trust’s area

6.—(1) In the case of an application under regulation 5(1)(b), where the applicant intends to change within the neighbourhood the premises from which he provides pharmaceutical services, being the same services as he intends to provide from the new premises, and the Primary Care Trust is satisfied that—

- (a) the change is a minor relocation; and
- (b) the provision of pharmaceutical services will not be interrupted (except for such period as the Primary Care Trust may for good cause allow),

the Primary Care Trust shall grant the application, subject to regulations 9(2) and 21(10) (and accordingly regulations 11 to 20 shall not apply).

(2) Except where paragraph (3) applies, a Primary Care Trust shall determine an application to which paragraph (1) relates in accordance with the procedures set out in, regulations 23, 24(1) and (3) to (6), 25, 26, 27 and 29.

(3) Where the minor relocation is to premises which are less than 500 metres by the most practicable route by foot from the applicant’s existing premises (“a minor relocation of less than 500 metres”), the Primary Care Trust shall—

- (a) determine the application without giving notice of the application under regulation 23 or hearing any oral representations under regulation 24; and
- (b) grant the application,

unless, within the period of 30 days beginning with the date of receipt of the application it notifies the applicant that it considers that it is desirable that the application be determined as if it were a minor relocation to premises which are 500 metres or more by the most practicable route by foot from the applicant’s existing premises (“a minor relocation of 500 metres or more”).

(4) Where the Primary Care Trust determines under paragraph (3) that an application for a minor relocation of less than 500 metres should be determined as if it were a minor relocation of 500 metres or more, it shall send the applicant a statement in writing setting out—

- (a) its decision and its reasons for it; and
- (b) the applicant’s right of appeal under paragraph (5).

(5) The applicant may within the period of 30 days beginning with the date of receipt of the notification under paragraph (4), appeal in writing to the Secretary of State against the decision notified to him under that paragraph.

(6) A notice of appeal under paragraph (5) shall contain a concise statement of the grounds of appeal.

(7) The Secretary of State may, when determining the appeal under paragraph (5)—

(a) S.I. 2002/2016, as amended by S.I. 2002/2469.

- (a) confirm the decision of the Primary Care Trust;
- (b) grant the appeal; or
- (c) grant the application.

(8) The Secretary of State shall notify the applicant and the Primary Care Trust in writing of his determination and shall include with the notification a written statement of the reasons for his determination.

(9) Where the determination of the Secretary of State is to grant the appeal, the Primary Care Trust shall within the period of 30 days beginning with the date of receipt of the notification under paragraph (8) determine the application in accordance with paragraph (3)(a).

Applications involving a minor relocation between neighbouring Primary Care Trusts

7.—(1) In the case of an application under regulation 5(1)(c), where—

- (a) the Primary Care Trust is satisfied that—
 - (i) the change is a minor relocation, and
 - (ii) the provision of pharmaceutical services will not be interrupted (except for such period as the Primary Care Trust may for good cause allow); and
- (b) the applicant consents to the removal of his name from the pharmaceutical list of the Primary Care Trust in which his existing premises are located in respect of those premises with effect from the date on which he commences to provide pharmaceutical services from his new premises,

the Primary Care Trust shall grant the application, subject to regulations 9(2) and 21(10) (and accordingly regulations 11 to 20 shall not apply).

(2) Subject to paragraph (3), a Primary Care Trust shall determine an application to which paragraph (1) relates in accordance with the procedures set out in, regulations 23, 24(1) and (3) to (6), 25, 26, 27 and 29.

(3) Where the minor relocation is to premises which are less than 500 metres by the most practicable route by foot from the applicant's existing premises ("a minor relocation of less than 500 metres"), the Primary Care Trust shall—

- (a) determine the application without giving notice of the application under regulation 23 or hearing any oral representations under regulation 24; and
- (b) grant the application,

unless within the period of 30 days beginning with the date of receipt of the application it notifies the applicant that it considers that it is desirable that the application be determined as if it were a minor relocation to premises which are 500 metres or more by the most practicable route by foot from the applicant's existing premises ("a minor relocation of 500 metres or more").

(4) Where the Primary Care Trust determines under paragraph (3) that an application for a minor relocation of less than 500 metres should be determined as if it were a minor relocation of 500 metres or more, it shall send the applicant a statement in writing setting out—

- (a) its decision and its reasons for it; and
- (b) the applicant's right of appeal under paragraph (5).

(5) The applicant may within the period of 30 days beginning with the date of receipt of the notification under paragraph (4), appeal in writing to the Secretary of State against the decision notified to him under that paragraph.

(6) A notice of appeal under paragraph (5) shall contain a concise statement of the grounds of appeal.

(7) The Secretary of State may, when determining the appeal under paragraph (5)—

- (a) confirm the decision of the Primary Care Trust;
- (b) grant the appeal; or
- (c) grant the application.

(8) The Secretary of State shall notify the applicant and the Primary Care Trust in writing of his determination and shall include with the notification a written statement of the reasons for his determination.

(9) Where the determination of the Secretary of State is to grant the appeal, the Primary Care Trust shall within the period of 30 days beginning with the date of receipt of the notification under paragraph (8) determine the application in accordance with paragraph (3)(a).

Applications involving a change of ownership

8.—(1) Where the applicant intends to provide pharmaceutical services at premises from which those services are, at the time of the application, provided by a person who is included in a pharmaceutical list, and the Primary Care Trust is satisfied that—

- (a) the same services will be provided from those premises; and
- (b) the provision of pharmaceutical services will not be interrupted (except for such period as the Primary Care Trust may for good cause allow),

the Primary Care Trust shall grant the application, subject to—

- (i) where the applicant is not already on that Primary Care Trust's pharmaceutical list, paragraph (2) and regulations 11, 19 and 21 (and accordingly regulations 12 to 18 and 20 shall not apply), or
- (ii) where the applicant is already on that Primary Care Trust's pharmaceutical list, paragraph (2) (and accordingly regulations 11 to 21 shall not apply).

(2) Where a temporary chemist wishes to make an application under regulation 5(1)(b) on behalf of the suspended chemist in whose place he is providing pharmaceutical services, and that application is to relate to his provision of those services as a temporary chemist, and the application is one falling within paragraph (1), he must, before making the application, obtain the written consent of the Primary Care Trust to the application.

(3) A Primary Care Trust shall determine an application to which paragraph (1) relates in accordance with the procedures set out in regulations 24(1) and (3) to (7), 26, 27, 28 and 29 and where paragraph (1)(i) applies, in addition regulation 24(2).

Applications following suspension from the list

9.—(1) Where—

- (a) the applicant intends to provide pharmaceutical services (otherwise than as a temporary chemist) from premises from which, at the time of the application, no services are being provided because the person who had undertaken to provide services from those premises is suspended from the pharmaceutical list; and
- (b) the Primary Care Trust is satisfied that the applicant will provide the same services as were provided by that person prior to his suspension,

the Primary Care Trust shall grant the application, subject to—

- (i) where the applicant is not already on that Primary Care Trust's pharmaceutical list, regulations 11, 19 and 21 (and accordingly regulations 12 to 18 and 20 shall not apply), or
- (ii) where the applicant is already on that Primary Care Trust's pharmaceutical list, regulation 11(2) (and accordingly regulations 11(1) and 12 to 21 shall not apply).

(2) A Primary Care Trust shall determine an application to which paragraph (1) relates in accordance with the procedures set out in regulations 24(1) and (3) to (7), 26, 27, 28 and 29 and where paragraph (1)(i) applies, in addition regulation 24(2).

(3) Where a temporary chemist wishes to make an application under regulation 5(1)(b) on behalf of the suspended chemist in whose place he is providing pharmaceutical services, that application shall be dealt with as if the application had been made by the suspended chemist whilst not

suspended from the pharmaceutical list (except that regulation 8(2) shall also apply in the case of an application falling within regulation 8(1)).

Right of return to pharmaceutical lists

10.—(1) This regulation applies if the Secretary of State makes a determination under regulation 4 of the National Health Service (Local Pharmaceutical Services and Pharmaceutical Services) (No. 2) Regulations 2002 that a person is to be given a right of return to a Primary Care Trust's pharmaceutical list on making an application for his name to be included in that list after ceasing to provide local pharmaceutical services under a pharmacy pilot scheme, and the conditions mentioned in paragraph (2) are satisfied.

(2) The conditions are that—

- (a) the period of time between the cessation of provision of local pharmaceutical services by the applicant and the commencement of provision of pharmaceutical services by the applicant will be such that the provision of such services will be continuous (except for such period as the Primary Care Trust may for good cause allow); and
- (b) the determination or determinations relevant to the application have not been invalidated by any subsequent determination, and that any conditions specified in the determination or determinations are satisfied.

(3) A person making an application under this regulation for inclusion of his name in a pharmaceutical list must apply to the Primary Care Trust giving the information set out in Part 1 of Schedule 4 while he is still providing local pharmaceutical services under a pharmacy pilot scheme, and in addition he must—

- (a) make clear that the application is made by virtue of this regulation; and
- (b) attach copies of all determinations relevant to the application.

(4) A person who meets the conditions specified in paragraph (7) must, in addition to the requirements of paragraph (3), provide the information, declarations and undertakings specified in Part 3 of Schedule 4.

(5) If a person has made an application in the manner described in paragraph (3) and (if applicable) (4) to a Primary Care Trust for his name to be included in its pharmaceutical list, the Primary Care Trust shall grant the application, subject to paragraph (6) and regulation 11(2).

(6) Notwithstanding the determination relevant to his application, if an applicant meets the conditions specified in paragraph (7), the provisions of regulations 19, 21, 26, 28 and 30 apply to his application under this regulation.

(7) The conditions referred to in paragraphs (4) and (6) are that—

- (a) the applicant is not, at the time of his application to a Primary Care Trust, already included in that Primary Care Trust's pharmaceutical list; and
- (b) the applicant was not, immediately before the date on which he commenced the provision of local pharmaceutical services, included in that Primary Care Trust's pharmaceutical list.

(8) Any conditions imposed by a Primary Care Trust under regulation 20 or by the Secretary of State under regulation 29(18)(b), 32(10)(b) or 38(14)(b) which are still in force by virtue of regulation 20(3) shall be unaffected by the grant of an application under this regulation.

(9) A Primary Care Trust must, as soon as is practicable, and in any event within the period of four months beginning with the date of receipt of the application unless the Primary Care Trust has good cause to require a longer period, give notice in writing of its decision on an application under this regulation to those persons or bodies listed in regulation 27(1)(a).

(10) Where a Primary Care Trust grants an application under this regulation, the applicant must be included in the relevant pharmaceutical list or lists only if, not less than 14 days before the expiry of six months after the date on which the grant was notified to him by the Primary Care Trust in accordance with paragraph (9), he notifies the Primary Care Trust, in the form set out in

Part 2 of Schedule 4, that he will, within the next 14 days, commence the provision of services in respect of which the application was made at the premises to which the application related.

(11) Where, at any time after making an application under this regulation, but before the expiry of the six months referred to in paragraph (10), the applicant notifies the Primary Care Trust that he intends to change within the neighbourhood the premises from which he intends to provide pharmaceutical services, being the same services as those named in the application, and the Primary Care Trust is satisfied that the change is a minor relocation, it may amend the premises named in the original application.

(12) For the purposes of paragraph (10), the date of the notification of a grant of an application is the day after the expiry of the period of 30 days beginning on the date on which notice of that decision is given under paragraph (9).

(13) Except as specified in paragraphs (6) and (8), regulations 5 to 9, 11(1) and 12 to 28 and 30 to 42 do not apply to an application under this regulation.

Refusal: general provisions

11.—(1) An application, other than one to which regulation 6, 7, 8(1)(b)(ii) or 9(3) applies, which is made by a person who qualified to have his name registered under the Pharmacy Act 1954(a) by virtue of section 4A(b) of that Act (qualification by European diploma) shall not be granted unless the applicant satisfies the Primary Care Trust that he has the knowledge of English which, in the interests of himself and persons making use of the services to which the application relates, is necessary for the provision of pharmaceutical services in the Primary Care Trust's area.

(2) A Primary Care Trust shall refuse an application in which a pharmacist does not offer to provide all of the essential services.

Necessary or desirable test

12.—(1) Subject to regulations 13, 19, 21, 25 and 26, an application shall be granted by the Primary Care Trust only if it is satisfied that it is necessary or desirable to grant the application in order to secure, in the neighbourhood in which the premises from which the applicant intends to provide the services are located, the adequate provision, by persons included in a pharmaceutical list, of the services, or some of the services, specified in the application ("the necessary or desirable test").

(2) Subject to regulations 25 and 26 and paragraph (4), in considering whether the necessary or desirable test is satisfied, a Primary Care Trust shall have regard in particular to—

- (a) whether or not any of the following services are already provided by persons in the neighbourhood in which the premises named in the application are located—
 - (i) any pharmaceutical services specified in the application provided by persons included in a pharmaceutical list, or any directed services the applicant agrees to provide if his name is included in the pharmaceutical list, or
 - (ii) any local pharmaceutical services provided under a pharmacy pilot scheme which are of the same description as any pharmaceutical services specified in the application;
- (b) whether the recipients of pharmaceutical services already have a reasonable choice with regard to—
 - (i) the pharmaceutical services provided in the neighbourhood in which the premises named in the application are located, by persons included in a pharmaceutical list, and
 - (ii) the persons included in a pharmaceutical list from whom such recipients may obtain pharmaceutical services in the neighbourhood in which the premises named in the application are located;

(a) 1954 c.61.

(b) Section 4A was inserted by S.I. 1987/2202.

- (c) any other information available to the Primary Care Trust which, in its opinion, is relevant to the consideration of the application; and
- (d) any representations received by the Primary Care Trust—
 - (i) under regulation 23(2) or (3), or
 - (ii) where the application is in respect of premises in a controlled locality, under regulation 33(4) from a person mentioned in regulation 33(2)(a) to (d) or (f) to (j) or (3)(a) to (d), (f) or (g).

(3) In considering whether the necessary or desirable test is satisfied, a Primary Care Trust may also have regard to any pharmaceutical services that the applicant proposes to provide in that neighbourhood in circumstances where he is not obliged to provide those services.

(4) The Primary Care Trust shall not take into account pharmaceutical services provided from premises at which pharmaceutical services are provided by a distance selling chemist when considering the pharmaceutical services already provided in the neighbourhood.

Exemption from the necessary or desirable test

13.—(1) Unless the applicant requests otherwise, or the premises to which his application relates are in a neighbourhood in which local pharmaceutical services are or are to be provided, regulation 12 shall not apply to an application in respect of—

- (a) premises which are in an approved retail area (within the meaning of regulation 15);
- (b) premises which the applicant is willing to keep open for at least 100 hours per week for the provision of pharmaceutical services;
- (c) premises which are in a new one-stop primary care centre (within the meaning of regulation 16); or
- (d) premises at which essential services are to be provided but the means of providing those services are such that all persons receiving them do so otherwise than at those premises (“distance selling premises”).

(2) As regards an application to which paragraph (1)(b) applies, if the application is granted—

- (a) it is a condition of the applicant’s inclusion in a pharmaceutical list (and so a term of service) that the premises to which the application relates are kept open for at least 100 hours per week for the provision of pharmaceutical services, and the Primary Care Trust may not vary or remove that condition; and
- (b) the Primary Care Trust may only remove a person from the pharmaceutical list for breach of that condition if—
 - (i) that person has repeatedly breached the condition, or is likely to breach the condition repeatedly, without good cause, or
 - (ii) the breach is, in all the circumstances, a serious breach and as a consequence of it the safety of a patient has been or may be put at serious risk.

(3) As regards an application to which paragraph (1)(a), (b) or (c) applies—

- (a) the application may only be granted if the applicant agrees to a condition of his inclusion in the pharmaceutical list that he will provide, where requested to do so by the Primary Care Trust, and at the premises to which the application relates, such directed services as the Primary Care Trust may specify; and
- (b) if the application is granted, it is a condition of the applicant’s inclusion in a pharmaceutical list (and so a term of service) that he provides, where requested to do so by the Primary Care Trust and at the premises to which the application relates, the directed services specified by the Primary Care Trust for the purposes of this paragraph (read with regulation 14).

(4) As regards an application to which paragraph (1)(d) applies, if the application is granted it is a condition of the applicant’s inclusion in a pharmaceutical list (and so a term of service) that—

- (a) he does not offer to provide pharmaceutical services to persons who are present at the premises to which the application relates; and
 - (b) the means by which he provides pharmaceutical services are such that the person receiving them does so otherwise than at the premises to which the application relates,
- and the Primary Care Trust may not vary or remove those conditions.

Variation of directed services in respect of exempted premises

14.—(1) A person in respect of whom a condition is imposed by virtue of regulation 13(3)(b) may apply to a Primary Care Trust for it to vary the directed services that it has specified as regards him for the purposes of that condition, but he may only do so after at least three years have elapsed—

- (a) since the condition was imposed in respect of him; or
- (b) during which the Primary Care Trust has not required him to provide the directed services.

(2) An application under paragraph (1) shall include the applicant's reasons for asking the Primary Care Trust to vary the condition concerned.

(3) The Primary Care Trust shall determine an application under paragraph (1) within 60 days of receiving it.

(4) In determining an application under paragraph (1), the Primary Care Trust shall—

- (a) specify, as regards the applicant, different or no directed services for the purposes of the condition imposed by virtue of regulation 13(3)(b) in respect of the premises to which the application relates, if this has the effect of either granting the application under paragraph (1) or granting it only in part; or
- (b) confirm that, as regards the applicant, the directed services that it has previously specified for the purposes of the condition imposed by virtue of regulation 13(3)(b) in respect of the premises to which the application relates are to remain unchanged.

(5) Where the Primary Care Trust is considering taking action under paragraph (4)(a), it shall consult the Local Pharmaceutical Committee before determining the application.

(6) A Primary Care Trust shall notify the applicant in writing of any action taken under paragraph (4), and where this has the effect of refusing an application under paragraph (1) or granting it in part, it shall send the applicant a statement in writing setting out—

- (a) the reasons for the refusal or, as the case may be, for granting the application only in part; and
- (b) the applicant's right of appeal under paragraph (7).

(7) The applicant may, within 30 days of receiving a notification pursuant to paragraph (6), appeal in writing to the Secretary of State against any action under paragraph (4) which has the effect of refusing an application under paragraph (1) or granting it only in part.

(8) A notice of appeal under paragraph (7) shall contain a concise statement of the grounds of appeal.

(9) The Secretary of State may, when determining an appeal, either confirm the action taken by the Primary Care Trust or take any action that the Primary Care Trust could have taken under paragraph (4).

(10) The Secretary of State shall notify the applicant in writing of his determination and shall in every case include with the notification a written statement of the reasons for the determination.

Approved retail areas

15.—(1) For the purposes of these Regulations, premises are in an approved retail area if they are in a retail area that has been approved by the Secretary of State under this paragraph for the purposes of the exemption in regulation 13(1)(a).

(2) Approval of an area under paragraph(1) shall only be granted if the Secretary of State is satisfied that it is in respect of—

- (a) an area—
 - (i) which comprises a discrete site or building which is a shopping centre, a retail park or retail premises, or
 - (ii) for which is planned a discrete site or building which, if the permitted development is carried out (and it may, at the time of the approval, be part carried out), will be a shopping centre, a retail park or retail premises,and such an area, for the purposes of these Regulations, is a “retail area”;
- (b) a retail area which is not or will not be part of—
 - (i) a primary shopping area which is or is part of—
 - (aa) a city, metropolitan or town centre; or
 - (bb) a district centre which performs the role of a city, metropolitan or town centre, or
 - (ii) an edge of centre location which relates to—
 - (aa) a city, metropolitan or town centre; or
 - (bb) a district centre which performs the role of a city, metropolitan or town centre,and in determining whether or not an area is a “primary shopping area” or an “edge of centre” location for the purposes of this sub-paragraph, regard shall be had to any relevant national planning policy guidance; and
- (c) a retail area which exceeds or will exceed the minimum size,

but approval under paragraph (1) shall otherwise be granted by the Secretary of State as he sees fit.

(3) For the purposes of paragraph (2)(c) a retail area exceeds or will exceed the minimum size if—

- (a) in the case of a shopping centre or retail premises, it is or will be, or incorporates or will incorporate, leasehold retail premises the gross floor space of which exceeds or will exceed 15,000 square metres; or
- (b) in the case of a retail park, it, together with any adjacent retail area, incorporates or will incorporate leasehold retail premises the gross floor space of which exceeds or will exceed 15,000 square metres.

(4) The Secretary of State shall publish, in such manner and at such intervals as he sees fit, a list of retail areas which are for the time being approved by him under paragraph (1).

(5) The Secretary of State may withdraw his approval under paragraph (1) of a retail area in appropriate circumstances.

New one-stop primary care centres

16.—(1) For the purposes of these Regulations, premises are in a new one-stop primary care centre if they are in a one-stop primary care centre which a Primary Care Trust on or after 1st April 2005 has for the first time included in its strategic service development plan (or if it has no such plan, in a written plan that achieves the same purpose as a strategic service development plan), at which on or after 1st April 2005—

- (a) the services of health care professionals will be provided for the first time; or
- (b) as a consequence of substantial new development or redevelopment, the services of a broad range of health care professionals will be provided for the first time.

(2) For the purposes of these Regulations, premises are a “one-stop primary care centre” if they are in a discrete site or building—

- (a) at which the services of a broad range of health care professionals is, or will be, regularly and frequently provided (together, where appropriate, with other health or social services);
- (b) at which there is, or will be, a provider of primary medical services with a patient list which comprises at least 18,000 patients; and
- (c) which is under the management or control of a consortium, and for these purposes a “consortium” is an association of persons or undertakings carrying on a business together with—
 - (i) a single management and equity structure, and
 - (ii) agreed written articles of association which commit them to running a one-stop primary care centre.

(3) In determining whether the requirements of paragraph (2)(a) are met, a Primary Care Trust shall have regard to the range and number of health care professionals (apart from those who are, or who are engaged or employed by, other chemists) who are available to provide services within its area.

Refusal: distance selling premises

17. A Primary Care Trust shall not grant an application to which regulation 13(1)(d) applies if the premises to which the application relates are on the same site or in the same building as the premises of a provider of primary medical services with a patient list.

Refusal: premises which are in a controlled locality but not in a reserved location

18.—(1) Paragraph (2) applies where the application is in respect of premises in a controlled locality and—

- (a) the Primary Care Trust has determined under regulation 35; or
- (b) on appeal it is determined,

that the premises from which the applicant wishes to provide pharmaceutical services are not in a reserved location.

(2) Subject to regulations 25 and 26 the Primary Care Trust—

- (a) shall refuse an application to the extent that it is of the opinion that to grant it would prejudice the proper provision of primary medical services, dispensing services, local pharmaceutical services or pharmaceutical services in any locality;
- (b) shall refuse an application under regulation 61 in relation to any part of the area specified in the application—
 - (i) which is not in a controlled locality, or
 - (ii) which is within 1.6 kilometres of any pharmacy;
- (c) shall refuse an application under regulation 61 in relation to any premises from which the doctor wishes to be authorised to dispense and which are within 1.6 kilometres of any pharmacy; and
- (d) may refuse an application in a case to which regulation 36(9) applies (notwithstanding that it would, if determining that application in isolation, grant it) where the number of applications is such, or the circumstances in which they are made are such, that to grant all of them or more than one of them would prejudice the proper provision of primary medical services, dispensing services, local pharmaceutical services or pharmaceutical services in any locality,

and any refusal of such an application may relate to all or any part of the area within the controlled locality.

Refusal: fitness to practise grounds

19.—(1) This regulation applies to an application to a Primary Care Trust—

- (a) under regulation 5, 40 or 54, where the applicant is not already on that Primary Care Trust's pharmaceutical list; and
- (b) under regulation 10, where the applicant meets the conditions specified in paragraph (7) of that regulation.

(2) A Primary Care Trust may refuse to grant an application to which this regulation applies if—

- (a) having considered the undertakings and declarations required by paragraphs 1, 2 and 3 of Part 3 of Schedule 4 and any other information in its possession in relation to the application, it considers that the applicant is unsuitable to be included in the list;
- (b) having checked the information provided by the applicant in accordance with paragraphs 4, 5 and 6 of Part 3 of Schedule 4, and any further information provided pursuant to the undertaking given in accordance with paragraph 12 of Part 3 of Schedule 4, it considers the applicant is unsuitable to be included in the list;
- (c) having contacted the referees nominated by the applicant in accordance with paragraph 7 of Part 3 of Schedule 4, it is not satisfied with the references given;
- (d) having checked with the National Health Service Counter Fraud and Security Management Service for any facts that it considers relevant relating to past or current fraud investigations involving or related to the applicant (and where the applicant is a body corporate, any director or superintendent of the applicant), and having considered these and any other facts in its possession relating to fraud involving or relating to the applicant (and where the applicant is a body corporate, any director or superintendent of the applicant), it considers these justify such refusal;
- (e) having checked with the Secretary of State for any facts that he considers relevant relating to past or current investigations or proceedings involving or relating to the applicant (and where the applicant is a body corporate, any director or superintendent of the applicant) and, having considered these and any other facts in its possession involving or relating to the applicant (and where the applicant is a body corporate, any director or superintendent of the applicant), it considers these justify such refusal; or
- (f) it considers that admitting the applicant to the list would be prejudicial to the efficiency of the service which he would undertake to provide.

(3) A Primary Care Trust must refuse to grant an application to which this regulation applies if—

- (a) the applicant (or where the applicant is a body corporate, any director or superintendent of the applicant) has been convicted in the United Kingdom of murder;
- (b) the applicant (or where the applicant is a body corporate, any director or superintendent of the applicant) has been convicted in the United Kingdom of a criminal offence, other than murder, which was committed after the date on which these Regulations come into force and has been sentenced to a term of imprisonment of over six months;
- (c) the applicant is the subject of a national disqualification;
- (d) the applicant has not updated his application in accordance with regulation 26(4); or
- (e) in a case to which regulation 30 applies, he does not notify the Primary Care Trust under regulation 30(4) that he wishes to be included in its pharmaceutical list subject to the specified conditions.

(4) Where the Primary Care Trust is considering refusal of an application under paragraph (2), it shall consider all facts which appear to it to be relevant and shall in particular take into consideration in relation to paragraph (2)(a), (b), (d) and (e)—

- (a) the nature of any offence, investigation or incident;
- (b) the length of time since any offence, incident, conviction or investigation;

- (c) whether there are other offences, incidents or investigations to be considered;
- (d) any action taken or penalty imposed by any licensing or regulatory body, the police or the courts as a result of any such offence, incident or investigation;
- (e) the relevance of any offence, investigation or incident to the provision by the applicant of pharmaceutical services and any likely risk to users of pharmaceutical services or to public finances;
- (f) whether any offence was a sexual offence to which Part 1 of the Sexual Offences Act 2003(a) applies, or if it had been committed in England and Wales, would have applied;
- (g) whether the applicant (and where the applicant is a body corporate, any director or superintendent of the applicant) has been refused admittance to, conditionally included in, removed, contingently removed or is currently suspended from any list or equivalent list on fitness to practise grounds, and if so, the facts relating to the matter which led to such action and the reasons given by the Primary Care Trust or equivalent body for such action; or
- (h) whether the applicant (and where the applicant is a body corporate, any director or superintendent of the applicant) was, at the time of the originating events, or has in the preceding six months been, a director or superintendent of a body corporate which has been refused admittance to, conditionally included in, removed or contingently removed from any list or equivalent list, or is currently suspended from any such list, on fitness to practise grounds, and if so, what the facts were in each such case and the reasons given by the Primary Care Trust or equivalent body in each case.

(5) When the Primary Care Trust takes into consideration the matters set out in paragraph (4), it shall consider the overall effect of all the matters being considered.

(6) An applicant may appeal to the FHSAA against a decision of the Primary Care Trust to refuse to grant his application—

- (a) to be included in the pharmaceutical list (including an application to be included as a temporary chemist); or
- (b) for preliminary consent to be included in that list,

on grounds specified in paragraph (2).

(7) An appeal must be made within the period of 28 days beginning with the date on which the Primary Care Trust notified the applicant of the decision under regulation 10(9), 27(1), 37(1) or 54(14) (as the case may be), and such an appeal shall be by way of redetermination of the Primary Care Trust's decision.

Imposition of conditions

20.—(1) Subject to regulations 22(4), 25 and 26 where—

- (a) the premises specified in an application under regulation 5(1) are in a controlled locality, or are not in a controlled locality but are within 1.6 kilometres of any part of any controlled locality in which reside patients for whom a doctor provides pharmaceutical services or for whom a GMS contractor or PMS contractor provides dispensing services; and
- (b) the granting of the application would, in the view of the Primary Care Trust, result in a significant change in the arrangements for the provision of pharmaceutical services, local pharmaceutical services or dispensing services in any part of a controlled locality,

the Primary Care Trust shall, where it grants the application, consider the conditions (if any) which are to be imposed in relation to that grant under paragraph (2), and pending the final determination of such conditions, shall not in consequence of the grant give notice to any doctor to discontinue the provision of pharmaceutical services or dispensing services to any patient.

(a) 2003 c.42.

(2) Where the Primary Care Trust considers that the provision of primary medical services by any provider of such services (other than itself) or pharmaceutical services by any chemist or local pharmaceutical services by any LPS chemist is likely to be adversely affected in consequence of a grant under paragraph (1), it may impose conditions to postpone, for such period as it thinks fit, the making or termination of arrangements under regulation 60 (or equivalent provision under the GMS Regulation or PMS Regulations) for the provision by a doctor or a GMS contractor or PMS contractor of pharmaceutical services or dispensing services to patients on the relevant patient list.

(3) Where a Primary Care Trust has imposed any conditions under paragraph (2), or the Secretary of State has imposed any conditions under regulation 29(18)(b), 32(10)(b) or 38(14)(b), those conditions shall be unaffected by the commencement or continuation of a pharmacy pilot scheme for the provision of local pharmaceutical services by the person whose application was granted subject to such conditions (or by a successor to that person who likewise provides local pharmaceutical services under that scheme).

Conditional inclusion relating to fitness to practise matters

21.—(1) This regulation applies to an application to a Primary Care Trust—

- (a) under regulation 5(1)(a), except an application in respect of which preliminary consent has previously been granted, where the premises specified in the application have the same location as that in respect of which preliminary consent has previously been granted;
- (b) under regulation 40 or 54, where the applicant is not already included in that Primary Care Trust's pharmaceutical list; or
- (c) under regulation 10, where the applicant meets the conditions specified in paragraph (7) of that regulation.

(2) Where a person makes an application to which this regulation applies, a Primary Care Trust may determine that, while he remains included in the pharmaceutical list, or while his preliminary consent has effect, he is to be subject to the imposition of conditions, having regard to the requirements in section 43ZA (conditional inclusion in medical, dental, ophthalmic and pharmaceutical lists) of the Act.

(3) A Primary Care Trust may vary the terms of service in relation to an applicant for the purpose of, or in connection with, the imposition of those conditions.

(4) A Primary Care Trust shall notify the applicant in writing as soon as is practicable of any conditions it intends to impose.

(5) When the Primary Care Trust notifies the applicant of any decision under this regulation, it shall inform him that if he wishes to exercise a right of appeal he must do so within the period of 28 days beginning with the date on which it gave him the notice informing him of its decision, and shall tell him how to make an appeal.

(6) A Primary Care Trust shall require the applicant to notify it, within 28 days of the date of the notification under paragraph (4)—

- (a) whether he agrees to the imposition of the conditions; or
- (b) whether he is appealing against that imposition of conditions under regulation 30.

(7) Paragraph (8) applies where—

- (a) a Primary Care Trust has granted an application for inclusion in its pharmaceutical list but imposed conditions on that grant; and
- (b) the applicant is considering whether to appeal, or has notified the Primary Care Trust that he wishes to appeal, but wishes to be included in the pharmaceutical list during the period until the time for appeal has expired or the appeal is decided.

(8) A Primary Care Trust shall include the applicant in its pharmaceutical list if—

- (a) it has received notification from him that he agrees to the imposition of the conditions during the period until the time for appeal has expired or the appeal is decided; and
- (b) the requirements of regulation 39 are satisfied.

(9) Where no notification is received from the applicant in accordance with paragraph (5), the Primary Care Trust shall deem him to have withdrawn his application.

(10) In the case of an application under regulation 5(1)(b) or (c), where an applicant is subject to conditions imposed in accordance with this regulation, or regulation 30, 42 or 43 a grant of his application shall be subject to those same conditions.

Relevant procedures for applications

22.—(1) An application which—

- (a) does not concern a controlled locality, or does concern a controlled locality but falls within paragraph (2); and
- (b) does not fall within regulations 6 to 10 or 54 (the procedures for which are referred to in regulation 6(2), 7(2), 8(3), 9(2), 10 and 54),

shall be dealt with in accordance with the procedures set out in paragraph (4) and regulations 12(2) to (4), 23 to 30.

(2) An application falls within this paragraph—

- (a) where the application is made under regulation 5(1)(b)(iii) except where the additional services which the person wishes to be able to provide include the provision of drugs; or
- (b) where—
 - (i) the applicant is seeking only to change within a controlled locality the premises at which he provides pharmaceutical services; and
 - (ii) the granting of the application would not, in the opinion of the Primary Care Trust, result in a significant change in the arrangements for the provision of pharmaceutical services (including by a person on the dispensing doctor list) or of local pharmaceutical services in any part of the locality.

(3) An application which—

- (a) concerns a controlled locality; and
- (b) does not fall within regulations 6 to 10 or 54 (the procedures for which are referred to in regulation 6(2), 7(2), 8(3), 9(2), 10 and 54), shall, unless it falls within paragraph (2), be dealt with in accordance with the procedures set out in—
 - (i) paragraph (4) and regulations 12(2) to (4), 25, 26, 28 and 30, and
 - (ii) regulations 31 to 38.

(4) Subject to regulations 25 and 26, where the premises specified in an application under regulation 5(1) are within 1.6 kilometres of the locality of another Primary Care Trust, the Primary Care Trust shall make enquiries as to controlled localities in that locality in order to determine—

- (a) whether the application is of the description specified in regulation 20(1); and
- (b) which controlled localities are to be considered for the purposes of paragraph (2)(b)(ii) or regulation 20(1)(b),

and where it is satisfied that there is a relevant controlled locality in that locality, it shall consult that other Primary Care Trust before forming a view for the purposes of paragraph (2)(b)(ii) or regulation 20(1)(b).

Notification of applications

23.—(1) This regulation applies where a Primary Care Trust receives an application which falls to be dealt with as mentioned in regulation 6, 7 or 22(1).

(2) Subject to regulations 25 and 26, the Primary Care Trust shall, as soon as is practicable, give notice in writing of the application to—

- (a) the Local Pharmaceutical Committee;
- (b) the Local Medical Committee;

- (c) any person who is included in a pharmaceutical list and whose interests might, in the opinion of the Primary Care Trust, be significantly affected if the application were granted;
- (d) any LPS chemist whose interests might, in the opinion of the Primary Care Trust, be significantly affected if the application were granted;
- (e) any Primary Care Trust or Local Health Board any part of whose area is within two kilometres of the premises;
- (f) any Patients' Forum serving the area of the Primary Care Trust; and
- (g) any other patient, consumer or community groups in the area of the Primary Care Trust that the Primary Care Trust considers has an interest in the provision of pharmaceutical services in the neighbourhood,

and any person so notified may, within 45 days from the date on which the notification was sent, or such longer period as the Primary Care Trust may allow in its notification, make representations in writing to the Primary Care Trust.

(3) A Primary Care Trust or Local Health Board which is notified under paragraph (2)(e) shall, as soon as is practicable, give notice in writing of the application to—

- (a) the Local Pharmaceutical Committee for its area;
- (b) the Local Medical Committee for its area;
- (c) any person whose name is included in a pharmaceutical list and whose interests might, in the opinion of that Primary Care Trust or Local Health Board, be significantly affected if the application were granted;
- (d) any LPS chemist whose interests might, in the opinion of that Primary Care Trust, be significantly affected if the application were granted;
- (e) any Patients' Forum or Community Health Council serving its area; and
- (f) any other patient, consumer or community groups in the area that the Primary Care Trust or Local Health Board considers has an interest in the provision of pharmaceutical services in the neighbourhood,

and any person so notified may, within 45 days from the date on which the notification was sent, make representations in writing to the Primary Care Trust to which the application was made.

(4) Any notice given under paragraph (2) or (3) shall include a notification of the right to make representations in accordance with that paragraph.

Determination of applications

24.—(1) Subject to the following paragraphs and regulations 25 and 26, the Primary Care Trust may determine an application in such manner as it thinks fit and may, if it considers that oral representations are unnecessary, determine the application without hearing any oral representations.

(2) Subject to regulations 25 and 26, in considering any application from an applicant who is not already included in that Primary Care Trust's pharmaceutical list (except an applicant who has applied under regulation 5(1)(c)), a Primary Care Trust shall—

- (a) check as far as reasonably practicable the information provided by the applicant, particularly that provided in accordance with paragraphs 1 to 6 of Part 3 of Schedule 4;
- (b) check with the National Health Service Counter Fraud and Security Management Service whether the applicant (and where the applicant is a body corporate, any director or superintendent of the applicant) has any record of fraud;
- (c) check with the Secretary of State as to any information held by him as to any record about past or current investigations or proceedings involving or related to the applicant (and where the applicant is a body corporate, any director or superintendent of the applicant);
- (d) take up and check the references provided under paragraph 7 of Part 3 of Schedule 4; and
- (e) consider whether there are grounds—

- (i) for refusing the application under regulation 19, or
- (ii) for imposing conditions in accordance with regulation 21.

(3) In any case where the Primary Care Trust decides to hear oral representations, it shall give the applicant and any person from whom it has received representations under regulation 23(2) or 23(3) not less than 14 days notice of the time and place at which the oral representations are to be heard.

(4) The applicant and any person mentioned in paragraph (3) may be assisted at any such hearing in the presentation of his representations by some other person, but no person shall be entitled to be heard in the capacity of counsel or solicitor.

(5) The procedure by which representations are heard shall be such as the Primary Care Trust may determine.

(6) No person—

- (a) who provides or assists in providing pharmaceutical services under Part 2 of the Act;
- (b) who is an LPS chemist;
- (c) who holds a GMS contract, or is a legal and beneficial shareholder in, or director or company secretary of, a company which holds a GMS contract, or is employed or engaged by a GMS contractor;
- (d) who is a PMS contractor, or is a legal and beneficial shareholder in, or director or company secretary of, a company which is a party to a PMS agreement, or is employed or engaged by a PMS contractor;
- (e) who is an APMS contractor, or is an officer, trustee or other person concerned with the management of a company, society, voluntary organisation or any other body which is an APMS contractor, or is employed or engaged by an APMS contractor;
- (f) who is employed or engaged by a Primary Care Trust for the purposes of providing primary medical services within a PCTMS practice; or
- (g) who is a party (other than a Primary Care Trust) to a pharmacy pilot scheme, or an officer or employee of such a person, or who provides or assists in providing local pharmaceutical services under a pharmacy pilot scheme,

shall take part in any decision under this regulation.

(7) Subject to regulations 25 and 26, the Primary Care Trust may, where it thinks fit, consider two or more applications together in relation to each other, and, where it proposes to do so, it shall give notice in writing to the applicants and any persons to whom copies of the application were sent under regulation 23(2).

Deferral of consideration of certain applications

25.—(1) Subject to paragraph (2), this regulation applies to—

- (a) an application under regulation 5(1);
- (b) such an application where the applicant has previously been granted preliminary consent, but where regulation 41(2) applies;
- (c) an application for preliminary consent under regulation 40; or
- (d) a notification under regulation 39(8),

relating to the provision of pharmaceutical services from premises or, in the case of a notification under sub-paragraph (d) above, the changed premises which are specified or described in a designation, or located within a neighbourhood specified in a designation.

(2) This regulation does not apply to—

- (a) an application under regulation 5(1) and to which regulation 8, 9 or 10 applies;
- (b) an application under regulation 5(1) where the applicant has previously been granted preliminary consent, and where all the conditions specified in regulation 41(1) are satisfied;

- (c) an application under regulation 40 and to which, by virtue of regulation 40(3), regulation 8 or 9 applies;
- (d) an application or notification in respect of which a determination by the Primary Care Trust has been made, where that determination is the subject of an appeal under regulation 29 or 38; or
- (e) an application or notification which was received by the Primary Care Trust more than 30 days before the date of the designation mentioned in paragraph (1).

(3) A Primary Care Trust may defer consideration or determination of an application or notification to which this regulation applies; but, subject to any power to defer contained in regulation 26, may no longer do so when the designation mentioned in paragraph (1) is cancelled, or varied in such a way that it no longer specifies or includes the premises in question.

(4) A Primary Care Trust must, as soon as is practicable, notify the applicant of a decision to defer consideration or determination of his application or notification, and send him a copy of the designation mentioned in paragraph (1).

(5) In this regulation, “designation” means a designation made by a Primary Care Trust under regulation 3(1) of the National Health Service (Local Pharmaceutical Services and Pharmaceutical Services) Regulations 2002(a).

Deferral of consideration of applications on fitness to practise grounds

26.—(1) A Primary Care Trust may defer consideration or determination of an application under regulation 5, 40 or 54, or an application under regulation 10 where the applicant meets the conditions specified in paragraph (7) of that regulation where—

- (a) there are, in respect of the applicant (and where the applicant is a body corporate, in respect of the applicant or a director or superintendent of the applicant)—
 - (i) criminal proceedings in the United Kingdom, or
 - (ii) proceedings elsewhere in the world relating to conduct, which, if it had occurred in the United Kingdom, would constitute a criminal offence,

which, if they resulted in a conviction, or the equivalent of a conviction, would be likely to lead to his removal from its pharmaceutical list, if he were to be included in it;

- (b) in respect of a body corporate of which the applicant is, or has in the preceding six months been, or was at the time of the originating events, a director or superintendent, there are—
 - (i) criminal proceedings in the United Kingdom, or
 - (ii) proceedings elsewhere in the world relating to conduct, which, if it had occurred in the United Kingdom, would constitute a criminal offence,

which, if they resulted in a conviction, or the equivalent of a conviction, would be likely to lead to his removal from its pharmaceutical list, if he were to be included in it;

- (c) there is an investigation anywhere in the world by the applicant’s (or where the applicant is a body corporate, any director or superintendent of the applicant’s) licensing or regulatory body or any other investigation (including one by another Primary Care Trust or equivalent body) relating to him in his professional capacity, that if adverse would be likely to lead to the removal of the applicant from the pharmaceutical list if he were to be included in it;
- (d) the applicant (and where the applicant is a body corporate, any director or superintendent of the applicant) is suspended from any list or equivalent list;
- (e) a body corporate of which the applicant (and where the applicant is a body corporate, any director or superintendent of the applicant) was, at the time of the originating events, a director or superintendent, is suspended from any list or equivalent list;

(a) S.I. 2002/888.

- (f) the FHSAA is considering an appeal by the applicant (and where the applicant is a body corporate, any director or superintendent of the applicant) against a decision of a Primary Care Trust or an equivalent body—
 - (i) to refuse an application by him for inclusion in any list or equivalent list,
 - (ii) to refuse an application by him for preliminary consent to be included in a pharmaceutical list held by a Primary Care Trust or equivalent body, or
 - (iii) to conditionally include him in, or to remove or contingently remove him from, any list kept by a Primary Care Trust,
 and if that appeal were to be unsuccessful the Primary Care Trust would be likely to remove the applicant from the pharmaceutical list if he were to be included in it;
- (g) the FHSAA is considering an appeal by a body corporate of which the applicant (and where the applicant is a body corporate, any director or superintendent of the applicant) was, at the time of the originating events, or has in the preceding six months been, a director or superintendent, against a decision of a Primary Care Trust or an equivalent body—
 - (i) to refuse an application by that body corporate for inclusion in its list,
 - (ii) to refuse an application by that body corporate for preliminary consent to be included in a pharmaceutical list held by a Primary Care Trust or equivalent body, or
 - (iii) to conditionally include it in, or to remove or contingently remove it from, any list kept by a Primary Care Trust or equivalent body,
 and if that appeal were to be unsuccessful the Primary Care Trust would be likely to remove the applicant from the pharmaceutical list if it were to be included in it;
- (h) the applicant (and where the applicant is a body corporate, any director or superintendent of the applicant) is being investigated by the National Health Service Counter Fraud and Security Management Service in relation to any fraud, where the result, if adverse, would be likely to lead to the removal of the applicant from the pharmaceutical list if he were to be included in it;
- (i) a body corporate, of which the applicant (and where the applicant is a body corporate, any director or superintendent of the applicant) was, at the time of the originating events, a director or superintendent, is being investigated by the National Health Service Counter Fraud and Security Management Service in relation to any fraud case, where the result if adverse would be likely to lead to the removal of the applicant from the pharmaceutical list if he had been included in it;
- (j) the FHSAA is considering an application from a Primary Care Trust or Local Health Board for a national disqualification of the applicant (and where the applicant is a body corporate, any director or superintendent of the applicant);
- (k) the FHSAA is considering an application from a Primary Care Trust or Local Health Board for a national disqualification of a body corporate of which the applicant (and where the applicant is a body corporate, any director or superintendent of the applicant) was, at the time of the originating events, a director or superintendent; or
- (l) in the case of an application under regulation 5(1)(b) or (c), a Primary Care Trust or equivalent body is considering removal or contingent removal of the applicant from any of its lists or equivalent lists on fitness to practise grounds, or the Primary Care Trust or equivalent body has taken a decision to remove or contingently remove the applicant from any of its lists or equivalent lists on fitness to practise grounds but that decision has yet to take effect.

(2) Subject to any power to defer consideration or determination of an application under regulation 25, a Primary Care Trust may only defer a decision under paragraph (1) until the outcome of the relevant event mentioned in that paragraph is known.

(3) A Primary Care Trust must, as soon as is practicable, notify the applicant in writing of a decision to defer consideration or determination of his application, and the reasons for this.

(4) Subject to regulation 25, once the outcome of the relevant event mentioned in paragraph (1) is known the Primary Care Trust shall notify the applicant that he must within 28 days of the date of the notification (or such longer period as it may agree)—

- (a) update his application; and
- (b) confirm in writing that he wishes to proceed with his application.

(5) If the applicant fails to update his application or confirm that he wishes to proceed in accordance with paragraph (4), the Primary Care Trust shall deem him to have withdrawn his application.

(6) Provided any additional information has been received within the 28 days or the time agreed, the Primary Care Trust shall notify the applicant as soon as possible—

- (a) that his application to be included has been successful; or
- (b) that it has decided to refuse the application or decided to impose conditions on his inclusion, and the reasons for that (including any facts relied upon), and of any right of appeal under regulation 19(6), 29 and 30.

Notification of decision

27.—(1) Subject to paragraph (2), a Primary Care Trust shall, as soon as practicable, and in any event within the period of four months beginning with the date of receipt of the application unless the Primary Care Trust has good cause to require a longer period, give notice in writing of its decision on an application under regulation 5(1), or of its decision whether or not to amend the premises named in the original application as mentioned in regulation 39(8)—

- (a) in the case of an application to which regulation 6, 7, 8, 9, 10 or 39(8) applies, to—
 - (i) the applicant,
 - (ii) any person who is included in a pharmaceutical list and whose interests might, in the opinion of the Primary Care Trust, be significantly affected by the decision,
 - (iii) any LPS chemist whose interests might, in the opinion of the Primary Care Trust, be significantly affected by the decision,
 - (iv) the Local Pharmaceutical Committee,
 - (v) the Local Medical Committee,
 - (vi) any Primary Care Trust or Local Health Board any part of whose locality is within two kilometres of the premises, and
 - (vii) any Patients' Forum serving the locality of the Primary Care Trust, and
 - (viii) any other patient, consumer or community groups in the area of the Primary Care Trust that the Primary Care Trust considers has an interest in the provision of pharmaceutical services in the neighbourhood; and
- (b) in the case of an application to which regulation 12 applies, or would apply but for an exemption under regulation 13 to—
 - (i) the applicant, and
 - (ii) any person who has made representations to the Primary Care Trust in accordance with regulation 23(2) or (3),

and shall include with the notice a statement of the reasons for the decision and of any rights of appeal arising under regulation 29.

(2) In the case of an application that involves a change of ownership and falls to be dealt with under regulation 8(1), for the period of four months specified in paragraph (1) there shall be substituted a period of 30 days.

(3) Any Primary Care Trust or Local Health Board which is notified under paragraph (1)(a)(vi) shall, as soon as practicable, give notice in writing of the decision and reasons to—

- (a) the Local Pharmaceutical Committee for its locality;
- (b) the Local Medical Committee for its locality;

- (c) any person whose name is included in the pharmaceutical list and whose interests might in the opinion of that Primary Care Trust or Local Health Board be significantly affected by the decision;
- (d) any LPS chemist whose interests might, in the opinion of that Primary Care Trust, be significantly affected by the decision;
- (e) any Patient’s Forum or Community Health Council notified under regulation 23(3)(e); and
- (f) any other patient, consumer or community groups in the area of the Primary Care Trust that the Primary Care Trust considers has an interest in the provision of pharmaceutical services in the neighbourhood,

and shall notify them of any rights of appeal arising under regulation 29.

(4) In this regulation, “decision” includes a decision to grant an application subject to conditions, where the applicant has agreed to the imposition of the conditions pursuant to regulation 21(6)(a).

Notifications by Primary Care Trusts to other persons

28.—(1) Where a Primary Care Trust—

- (a) refuses to grant an application on grounds specified in regulation 19; or
- (b) imposes conditions under regulation 21, 30, 42 or 43,

it shall notify the persons and bodies specified in paragraph (2), and shall additionally notify those specified in paragraph (3) if so requested by those persons or bodies in writing (including electronically), of the matters set out in paragraph (4); and the applicant or chemist in relation to whom such a decision has been taken under this paragraph is called a “pharmaceutical practitioner” in this regulation.

(2) Where paragraph (1) applies, a Primary Care Trust shall notify—

- (a) the Secretary of State;
- (b) any Primary Care Trust or equivalent body that has on any of its lists or equivalent lists—
 - (i) the pharmaceutical practitioner, or
 - (ii) a body corporate of which the pharmaceutical practitioner is a director or superintendent,

or any Primary Care Trust or equivalent body that is considering an application for inclusion in, or for preliminary consent to be included in, any of its lists or equivalent lists from such a practitioner, director, superintendent or body corporate;

- (c) the Scottish Executive;
- (d) the National Assembly for Wales;
- (e) the Northern Ireland Executive;
- (f) the Royal Pharmaceutical Society of Great Britain, the Pharmaceutical Society of Northern Ireland or any other appropriate regulatory body;
- (g) the Local Pharmaceutical Committee for the Primary Care Trust’s area;
- (h) the National Patient Safety Agency^(a); and
- (i) where it is a fraud case, the National Health Service Counter Fraud and Security Management Service.

(3) The persons or bodies who may request to be additionally notified in accordance with paragraph (1) are—

- (a) persons or bodies that can establish that they—

^(a) The National Patient Safety Agency is established as a Special Health Authority by the National Patient Safety Agency (Establishment and Constitution) Order 2001 (S.I. 2001/1743).

- (i) are or were employing the pharmaceutical practitioner, are using or have used his services (or where the pharmaceutical practitioner is a body corporate, any director or superintendent of that practitioner) in a professional capacity, or
 - (ii) are considering employing or using the services of the pharmaceutical practitioner (or where the pharmaceutical practitioner is a body corporate, any director or superintendent of that practitioner) in a professional capacity; and
- (b) a partnership any of whose members provide or assist in the provision of pharmaceutical services and can establish that the pharmaceutical practitioner is or was a member of the partnership, or that it is considering inviting him to become such a member.
- (4) The matters referred to in paragraph (1) are—
- (a) the name, address and date of birth of the pharmaceutical practitioner;
 - (b) where the pharmaceutical practitioner is a body corporate, the name and registered office of the body corporate;
 - (c) any professional registration number of the pharmaceutical practitioner;
 - (d) the date and a copy of the decision of the Primary Care Trust; and
 - (e) a contact name of a person in the Primary Care Trust for further enquiries.
- (5) The Primary Care Trust shall send to the pharmaceutical practitioner concerned a copy of any information about him provided to the persons or bodies specified in paragraphs (2) and (3) and any correspondence with those persons or bodies relating to that information.
- (6) Where the Primary Care Trust has notified any of the persons or bodies specified in paragraph (2) or (3) of the matters set out in paragraph (4), it may in addition, if so requested by that person or body, notify that person or body of any evidence that was considered, including representations made by the pharmaceutical practitioner.
- (7) Where a Primary Care Trust is notified by the FHSAA that it has imposed a national disqualification on a pharmaceutical practitioner whom the Primary Care Trust has removed from its list, it shall notify the persons or bodies specified in paragraph (2)(b), (g), (h) and (i) and paragraph (3).
- (8) Where a decision is changed on review or appeal, or a suspension lapses, the Primary Care Trust shall notify any person or body that was notified of the original decision of the later decision, or of the fact that the suspension has lapsed.

Appeals

- 29.—(1) This regulation shall not apply to any right of appeal specified—
- (a) in regulation 6(5) or 7(5);
 - (b) in regulation 19(6); or
 - (c) in regulation 30.
- (2) Where a Primary Care Trust—
- (a) has determined an application to which regulation 6(1), 7(1), 8, 9 and 10 applied; or
 - (b) made a decision whether or not to amend the premises named in the original application as mentioned in regulation 39(8),
- the applicant and any person who has been notified of the decision under regulation 27(1)(a)(ii) or (iii) or regulation 27(3)(c) or (d) may appeal to the Secretary of State.
- (3) Where a Primary Care Trust has determined an application to which regulation 12 applied, or would apply but for an exemption under regulation 13, the persons who may appeal to the Secretary of State are—
- (a) the applicant; and
 - (b) except in the case of an application to which regulation 13(1) applies, any person who—
 - (i) was given notice of the application under regulation 23(2)(c) or (d) or regulation 23(3)(c) or (d), and

- (ii) made representations to the Primary Care Trust in accordance with regulation 23(2) or (3).

(4) Where a Primary Care Trust refuses to allow an extension to the period within which an applicant is to notify the Primary Care Trust that he will commence provision of the services, as mentioned in regulation 39(2), the applicant may appeal to the Secretary of State.

(5) Where a Primary Care Trust has notified an applicant that he is required to commence provision of the services, as mentioned in regulation 39(3), the applicant may appeal to the Secretary of State.

(6) Any appeal under this regulation shall be made by sending to the Secretary of State a notice of appeal in writing—

- (a) within 30 days from the date on which the Primary Care Trust sent its decision to the appellant; or
- (b) in the case of an appeal against a determination to which regulation 6, 7, 8, 9 and 10 applied, or a decision pursuant to regulation 39(8), such longer period as the Secretary of State may for reasonable cause allow.

(7) Where in determining an application, a Primary Care Trust has, pursuant to regulation 24(7), considered that application together with one or more other applications, any of the applicants and any of the persons mentioned in paragraph (2) or (3) may appeal against the determination of any of the applications, and where the Secretary of State receives appeals against two or more of the determinations, those appeals shall be considered together.

(8) The Secretary of State may consider together two or more appeals against a Primary Care Trust provided that those appeals relate to an application within the same neighbourhood which fell to be granted under regulation 6(1), 7(1) or 8(1).

(9) Any notice of appeal made under this regulation shall contain a concise statement of the grounds of appeal.

(10) If the Secretary of State, after considering the notice of appeal, is of the opinion that it discloses no reasonable grounds of appeal, or that the appeal is otherwise vexatious or frivolous, he may determine the appeal by dismissing it.

(11) Unless paragraph (10) applies, the Secretary of State shall send a copy of the notice of appeal to the Primary Care Trust whose determination is appealed against and—

- (a) in the case of an appeal to which paragraph (2) or (4) relates, to the persons mentioned in regulation 27(1)(a);
- (b) in the case of an appeal to which paragraph (3) relates, to the persons mentioned in regulation 27(1)(b); or
- (c) in the case of an appeal to which regulation 9(1) or (3) or 54(24) relates, to the applicant and to the suspended chemist.

(12) Any person to whom a copy of the notice of appeal is sent pursuant to paragraph (11) may, within 30 days from the date on which the notice was sent to him, make representations in writing to the Secretary of State on appeal.

(13) The Secretary of State may require an oral hearing before he determines the appeal.

(14) The Secretary of State shall, where he requires an oral hearing, appoint one or more persons to hear the appeal and to report to him on it.

(15) The procedure of any oral hearing shall be determined by the person or persons hearing the appeal.

(16) An oral hearing shall take place at such time and place as the Secretary of State may direct, and notice of the hearing shall be sent, not less than 14 days before the date fixed for the hearing, to the appellant and to any person to whom a copy of the notice of appeal was sent under paragraph (11).

(17) The appellant and any person to whom a notice of the hearing is sent under paragraph (16) may attend the hearing and be heard in person or by counsel, solicitor or other representative, and

the Primary Care Trust may be represented at the hearing by any duly authorised officer or member, or by counsel or solicitor.

(18) On determining an appeal under this regulation, the Secretary of State shall either—

- (a) allow the appeal;
- (b) may, in a case where the Primary Care Trust, on determining the application, considered the question whether to impose conditions to postpone the making or termination of arrangements under regulation 60 (or equivalent provision under the GMS Regulations or PMS Regulations) for the provision by a doctor or GMS contractor or PMS contractor of pharmaceutical services or dispensing services to patients on the relevant patient list, himself impose conditions to postpone for such period as he thinks fit, the making or termination of such arrangements;
- (c) shall, in a case where that question was not considered by the Primary Care Trust when it determined the application, remit the question to the Primary Care Trust for determination;
- (d) confirm the decision of the Primary Care Trust; or
- (e) where paragraph (5) applies, specify a date for the commencement of pharmaceutical services by the appellant.

(19) The Secretary of State shall, as soon as practicable, send to the appellant and to any person to whom a copy of the notice of appeal was sent pursuant to paragraph (11) and who made representations under paragraph (12), notice in writing of his decision on the appeal and shall include in the notice a statement of his reasons for the decision and of his findings of fact.

Appeals against imposition of conditions and related decisions

30.—(1) An applicant (or a person whose application has been granted subject to conditions, as the case may be) may appeal to the FHSAA against any decision of the Primary Care Trust to impose conditions, or any particular condition, on him in accordance with regulation 21(2); and the appeal shall be by way of redetermination of the Primary Care Trust's decision.

(2) An appeal under this regulation must be made within 28 days of the notification of the decision being appealed against.

(3) On appeal the FHSAA may make any decision which the Primary Care Trust could have made, and shall notify the appellant and the Primary Care Trust in writing as soon as is practicable of the decision.

(4) Where the decision of the FHSAA on appeal is that conditions be imposed on the appellant, whether or not those conditions are identical with the conditions imposed by the Primary Care Trust, the Primary Care Trust shall require the appellant to notify it, within 28 days of the date of the notification to him under paragraph (3), as to whether he agrees to the imposition of the conditions.

(5) Where no notification is received from the appellant in accordance with paragraph (4), or the appellant notifies the Primary Care Trust that he does not agree to the imposition of the conditions, the Primary Care Trust shall deem him to have withdrawn his application and shall remove his name from its pharmaceutical list if his name was included pursuant to regulation 21(8).

(6) Subject to regulation 21(8), any decision of the Primary Care Trust that may be the subject of an appeal under this regulation shall not have effect until the FHSAA has determined any appeal against it or any time for appeal has expired.

Determination that an area is a controlled locality

31.—(1) Where, before the coming into force of these Regulations, an area was a controlled locality for the purposes of the 1992 Regulations, subject to the provisions of this regulation, that area shall continue to be a controlled locality.

(2) Subject to paragraph (10), a Primary Care Trust may at any time consider and determine whether or not an area is rural in character, and paragraphs (7) and (8)(b) and (c) shall apply as they apply to an application under paragraph (3).

(3) A Local Medical Committee or a Local Pharmaceutical Committee may at any time apply in writing to a Primary Care Trust to consider and determine whether or not an area specified in the application is rural in character.

(4) On receiving an application under paragraph (3), the Primary Care Trust shall, subject to paragraph (10), consider and determine whether or not the area specified in the application or any part of such area, is rural in character.

(5) The Primary Care Trust shall, before making a determination under this regulation, give notice in writing to the Local Medical Committee, the Local Pharmaceutical Committee and any provider of primary medical services or chemist, or LPS chemist who, in the opinion of the Primary Care Trust, may be affected by the determination, and shall inform them that they may make representations in writing within 30 days from the date on which the notice was sent.

(6) Where the Primary Care Trust determines that any area or part of an area is or is not rural in character, it shall consider whether the provision of primary medical services by any provider of primary medical services (except itself), or pharmaceutical services by any chemist (other than a distance selling chemist), or local pharmaceutical services by any LPS chemist, is likely to be adversely affected in consequence of that determination.

(7) The Primary Care Trust shall determine the boundaries of any area, or part of an area, referred to in the application which it determines to be rural in character, and—

- (a) any area determined to be rural in character by the Primary Care Trust or, on appeal under regulation 32, by the Secretary of State, shall be a controlled locality; and
- (b) the Primary Care Trust shall delineate precisely the boundaries of any controlled locality on a map, and shall publish the map.

(8) Any area forming part of an area referred to in an application under paragraph (3) which is determined not to be rural in character shall not be or, as the case may require, shall cease to be, a controlled locality.

(9) The Primary Care Trust shall not in consequence of a determination under paragraph (4)—

- (a) include any particulars in a pharmaceutical list;
- (b) give notice to a doctor pursuant to regulation 60(7);
- (c) give notice to a GMS contractor or PMS contractor pursuant to an equivalent provision to regulation 60(7) under the GMS Regulations or PMS Regulations; or
- (d) determine an application under regulation 36,

during the period for bringing an appeal or pending the determination of any such appeal.

(10) Subject to paragraph (11), where the question whether or not an area is rural in character has been determined—

- (a) by a Primary Care Trust under this regulation; or
- (b) on appeal under regulation 32,

that question shall not again be considered in relation to that area or any part of it during the period of five years immediately following the date of the determination.

(11) A question to which paragraph (10) applies may be considered by a Primary Care Trust during the period referred to in that paragraph only where it is satisfied, whether on an application under paragraph (3) or otherwise, that there has been a substantial change in circumstances in relation to the area in question, or the relevant part of it, since the question was last determined.

(12) The Primary Care Trust shall, upon any determination by it under this regulation, give to the persons mentioned in paragraph (5) notice in writing of its determination and of the reasons for it, and shall inform them that they may appeal to the Secretary of State in accordance with regulation 32.

Appeals relating to rurality of an area

32.—(1) Where a Primary Care Trust—

- (a) has determined, pursuant to regulation 31, that an area is, or is not, rural in character;
- (b) has refused to consider that question on the ground that it is not satisfied as mentioned in paragraph (11) of that regulation; or
- (c) has determined under these Regulations that it should, or should not, postpone the making or termination of arrangements, as mentioned in regulation 20(2),

the Local Medical Committee, the Local Pharmaceutical Committee or a provider of primary medical services under Part 1 of the Act, chemist or LPS chemist who is required to be given notice by the Primary Care Trust under regulation 31(5) may appeal to the Secretary of State against any such determination or, as the case may be, refusal, by giving notice of appeal in accordance with paragraph (2).

(2) Any notice of appeal under paragraph (1) shall be sent to the Secretary of State, within 30 days of the date on which the decision of the Primary Care Trust was sent to the person making the appeal, and shall contain a concise statement of the grounds of appeal.

(3) The Secretary of State shall, on receipt of any notice of appeal under this regulation, send copies thereof to the Primary Care Trust and to all the persons to whom it has given notice of its determination under regulation 31 (12).

(4) The Primary Care Trust and the persons to whom the notice of appeal was sent under paragraph (3) may, within 30 days from the date on which the Secretary of State sent copies to them of the notice of appeal under this regulation, make representations in writing to him on the appeal.

(5) The Secretary of State may require an oral hearing before he determines an appeal under this regulation.

(6) The Secretary of State shall, where he requires an oral hearing, appoint one or more persons to hear the appeal and to report to him on it.

(7) The procedure at any oral hearing shall be determined by the person or persons hearing the appeal.

(8) An oral hearing shall take place at such time and place as the Secretary of State may direct, and notice of the hearing shall be sent, not less than 14 days before the date fixed for the hearing, to the appellant and to any person to whom a copy of the notice of appeal was sent under paragraph (3).

(9) The appellant and any person to whom a notice of the hearing is sent under paragraph (8) may attend the hearing and be heard in person or by counsel, solicitor or other representative, and the Primary Care Trust may be represented at the hearing by any duly authorised officer or member, or by counsel or solicitor.

(10) On determining an appeal under this regulation, the Secretary of State—

- (a) shall, where he allows an appeal against a refusal mentioned in paragraph (1)(b), also determine the question whether or not the relevant area is rural in character;
- (b) may, in a case where the Primary Care Trust, on determining the application, considered the question whether to postpone the making or termination of arrangements under regulation 60 (or equivalent provision under the GMS Regulations or PMS Regulations) for the provision by a doctor or a GMS contractor or PMS contractor of pharmaceutical services or dispensing services to patients, himself postpone, for such a period as he thinks fit, the making or termination of such arrangements;
- (c) shall, in a case where that question was not considered by the Primary Care Trust when it determined the application, remit the question to the Primary Care Trust for determination.

(11) The Secretary of State shall, upon the determination by him of an appeal under this regulation, give notice of the decision in writing, together with his reasons for it, to all the persons to whom the notice of appeal was sent under paragraph (3).

Notification of an application in respect of premises in a controlled locality

33.—(1) This regulation applies where a Primary Care Trust receives an application which falls to be dealt with as mentioned in regulation 22 (3) or 35(7)(b).

(2) Subject to regulations 25 and 26, the Primary Care Trust shall send a notice of the application and a copy of the application to—

- (a) the Local Pharmaceutical Committee;
- (b) the Local Medical Committee;
- (c) any person who is included in a pharmaceutical list and whose interests might, in the opinion of the Primary Care Trust, be significantly affected if the application were granted;
- (d) any LPS chemist whose interests might, in the opinion of the Primary Care Trust, be significantly affected if the application were granted;
- (e) any person (except itself) who is a provider of primary medical services within the area of the Primary Care Trust, or whose name is included in the dispensing doctor list of the Primary Care Trust, who might, in the opinion of the Primary Care Trust, be significantly affected if the application were granted;
- (f) any Primary Care Trust or Local Health Board any part of whose area is within two kilometres of the premises;
- (g) any Patients' Forum serving the locality of the Primary Care Trust;
- (h) any other patient, consumer or community groups in the area of the Primary Care Trust that the Primary Care Trust considers has an interest in the provision of pharmaceutical services in the neighbourhood;
- (i) any other Primary Care Trust part of whose area is or might form part of a reserved location; and
- (j) where the determination is required to be made by regulation 61, any other Primary Care Trust part of whose area is within 1.6 kilometres of the premises from which the doctor wishes to dispense.

(3) Subject to regulations 25, and 26 where a Primary Care Trust or Local Health Board is sent a copy of an application under paragraph (2)(f) it shall, as soon as practicable, send a copy to—

- (a) the Local Pharmaceutical Committee for its locality;
- (b) the Local Medical Committee for its locality;
- (c) any person whose name is included in the pharmaceutical list, and whose interests might, in the opinion of that Primary Care Trust or Local Health Board, be significantly affected if the application were granted;
- (d) any LPS chemist whose interests might, in the opinion of that Primary Care Trust, be significantly affected if the application were granted;
- (e) any person (except itself) who is a provider of primary medical services or whose name is included in the dispensing doctor list who might, in the opinion of that Primary Care Trust or Local Health Board, be significantly affected if the application were granted; and
- (f) any Patients' Forum or Community Health Council serving its area;
- (g) and any other patient, consumer or community groups in the area of the Primary Care that the Primary Care Trust considers has an interest in the provision of pharmaceutical services in the neighbourhood.

(4) Any person to whom a Primary Care Trust or Local Health Board has sent a copy of the application may, within 30 days of the date on which that copy was sent to him make representations in writing to the Primary Care Trust to which the application was made.

(5) Any other person who considers that he might be affected by the decision may, within such reasonable period as the Primary Care Trust to whom the application was made may allow, make representations in writing to it.

Decision not to consider an application in respect of premises in a controlled locality

34.—(1) Subject to paragraph (2), a Primary Care Trust shall not consider under regulation 36—

- (a) any application for outline consent under regulation 61 where, during the relevant period, an application made under that regulation or any corresponding provision of directions relating to dispensing services in respect of the same area has been finally refused;
- (b) any application to which regulation 40 applies, where the location of the premises at which the pharmacist intends to provide pharmaceutical services is in a controlled locality and—
 - (i) is in an area in respect of which an application under regulation 61 or any corresponding provision of directions relating to dispensing services was finally granted during the relevant period, or
 - (ii) is within 1.6 kilometres of the location of premises in respect of which an application to which regulation 22(1) or (3) applies was finally refused during the relevant period;
- (c) any request by a chemist under regulation 35(5) for a determination as to whether premises are in a reserved location, where the application in relation to the premises was refused by the operation of regulation 18(2) during the relevant period; or
- (d) any application by a doctor for outline consent or premises approval for premises—
 - (i) in respect of which outline consent or premises approval has been refused by the operation of regulation 18(2) during the relevant period, or
 - (ii) which are within 1.6 kilometres of such premises.

(2) A Primary Care Trust may at any time consider an application to which paragraph (1) applies where it is satisfied that, since the date of the refusal or, as the case may be, grant referred to in paragraph (1)(a) or (b), or, where there has been more than one such refusal or grant during the relevant period, the last such refusal or grant, there has been a substantial change of circumstances affecting the controlled locality.

(3) In this regulation, “relevant period” means the period of 5 years immediately preceding the making of the application.

Pharmaceutical services in reserved locations

35.—(1) Subject to regulation 34, the Primary Care Trust shall, when the period for representations has expired under regulation 33 determine whether the premises, or relevant location, from which the applicant wishes to provide pharmaceutical services, at the date of the receipt of the application by the Primary Care Trust, are in a reserved location.

(2) In this regulation—

- (a) subject to paragraph (3), a “reserved location” means that the number of individuals on all of the patient lists for the area which is within 1.6 kilometres of the premises, or from the relevant location, as the case may be, is less than 2750; and
- (b) the “relevant location” means, where the location of the premises from which the pharmaceutical services are to be provided is specified in writing by the applicant before the Primary Care Trust make its determination, that location, and where that location is not so specified, the best estimate the Primary Care Trust is able to make of where those premises may be.

(3) Premises, or a relevant location, are not in a reserved location where the Primary Care Trust considers that there are circumstances, including but not limited to the age or degree of infirmity of the individuals referred to in paragraph (2), why the extent of use of pharmaceutical services if a pharmacy were to operate from the premises or from the relevant location would be similar to or greater than might be expected if the number of individuals mentioned in paragraph (1)(a) were 2750 or more.

(4) Before reaching its opinion under paragraph (3) the Primary Care Trust shall invite and consider representations as to whether paragraph (3) may apply from those persons mentioned in regulation 33(2).

(5) Subject to regulation 34(1)(c), where it has been determined by the Primary Care Trust or on appeal by the Secretary of State, in relation to premises, or a relevant location, from which pharmaceutical services are to be, or are being, provided, that those premises are in a reserved location, the chemist in relation to those premises, or that relevant location, may make an application in writing for the Primary Care Trust to make a further determination as to whether, on the date the request is made, that is, the date stated on it, those premises are, or that the relevant location is, in a reserved location.

(6) Where, in making a further determination applied for in accordance with paragraph (5) the Primary Care Trust would determine that those premises are, or that relevant location is, not in a reserved location, or there is an appeal against a determination by the Primary Care Trust and it is determined on the appeal that premises are not, or that relevant location is not, in a reserved location—

- (a) the Primary Care Trust shall determine that the premises are, or the relevant location is, to be treated for the purposes of these Regulations as if they were in a reserved location, where it is of the opinion that not to do so would prejudice the proper provision of primary medical services (other than those provided by the Primary Care Trust itself), dispensing services or pharmaceutical services in any locality; or
- (b) if the Primary Care Trust considers that the provision of primary medical services by a provider of primary medical services (other than one employed by the Primary Care Trust), or pharmaceutical services by any chemist, is likely to be adversely affected by a determination that the premises are not in a reserved location, it shall make such a determination but may impose conditions to postpone, for such period as it thinks fit, the making or termination of arrangements under regulation 60 (or equivalent provision under the GMS Regulations or PMS Regulations) for the provision by a doctor or a GMS contractor or PMS contractor of pharmaceutical services or dispensing services to patients.

(7) A determination required by—

- (a) paragraph (1) shall be made in accordance with this regulation, and with regulations 34, 36 and 37; and
- (b) paragraph (5) shall be made in accordance with this regulation and regulations 33, 34, 36 and 37.

(8) Where—

- (a) there is an appeal against a determination made by the Primary Care Trust that premises are, or a relevant location is, in a reserved location; and
- (b) it is determined by the appeal that the premises are not, or relevant location is not, in a reserved location,

the Primary Care Trust shall redetermine the application.

(9) The Primary Care Trust shall delineate precisely the boundaries of any reserved location it has determined under paragraph (1) or (5) on a map, and shall publish the map.

Determination of applications in respect of controlled localities

36.—(1) Subject to regulations 25 and 26, the Primary Care Trust may make a determination in such manner as it thinks fit and may, if it considers that oral representations are unnecessary, make the determination without hearing any oral representations.

(2) When determining an application, the Primary Care Trust shall consider whether the provision of primary medical services by any provider of such services (except itself) or pharmaceutical services by any chemist or local pharmaceutical services by any LPS chemist is likely to be adversely affected in consequence of that grant, and whether any conditions should be imposed in accordance with regulation 20(2).

(3) Subject to regulations 25 and 26, in considering any application made under regulation 5 from an applicant who is not already included in that Primary Care Trust's pharmaceutical list, a Primary Care Trust shall—

- (a) check as far as practicable the information provided by the applicant, particularly that provided in accordance with paragraphs 1 to 6 of Part 3 of Schedule 4;
- (b) check with the National Health Service Counter Fraud and Security Management Service whether the applicant (and where the applicant is a body corporate, any director or superintendent of the applicant) has any record of fraud;
- (c) check with the Secretary of State as to any information held by him as to any record about past or current investigations or proceedings involving or related to the applicant (and where the applicant is a body corporate, any director or superintendent of the applicant);
- (d) take up and check any references provided under paragraph 7 of Part 3 of Schedule 4; and
- (e) consider whether there are grounds—
 - (i) for refusing the application under regulation 19, or
 - (ii) for imposing conditions in accordance with regulation 21.

(4) In any case where the Primary Care Trust decides to hear oral representations, it shall give the applicant and any person from whom it has received representations under regulation 33(4) or (5) not less than 14 days notice of the time and place at which the representations are to be heard.

(5) The Primary Care Trust may invite any other person to give oral evidence as it thinks fit.

(6) The applicant and any person mentioned in paragraph (4) may be assisted at any such hearing in the presentation of his representations by some other person, but no person shall be entitled to be heard in the capacity of counsel or solicitor.

(7) The procedure by which representations are heard shall be such as the Primary Care Trust may determine.

(8) No person—

- (a) who provides or assists in providing pharmaceutical services under Part 2 of the Act;
- (b) who is a LPS chemist;
- (c) who is a GMS contractor, or is a legal and beneficial shareholder in, or director or company secretary of, a company which is a GMS contractor, or is employed or engaged by a GMS contractor;
- (d) who is a PMS contractor, or is a legal and beneficial shareholder in, or director or company secretary of, a company which is a PMS contractor, or is employed or engaged by a PMS contractor;
- (e) who is an APMS contractor, or is an officer, trustee or other person concerned with the management of a company, society, voluntary organisation or any other body which is an APMS contractor, or is employed or engaged by an APMS contractor;
- (f) is employed or engaged by a Primary Care Trust for the purposes of providing primary medical services within a PCTMS practice; or
- (g) who is a party (other than a Primary Care Trust) to a pharmacy pilot scheme, or a director, officer or employee of such a person, or who provides or assists in providing local pharmaceutical services under a pharmacy pilot scheme,

shall take part in any decision under this regulation.

(9) Subject to regulations 25 and 26, the Primary Care Trust may, where it thinks fit, where two or more determinations fall to be made which relate to each other, make those determinations together, and, where it proposes to do so, it shall so inform the applicants and the persons to whom copies of the applications were sent under regulation 33.

Notification of decision in respect of applications in controlled localities

37.—(1) The Primary Care Trust shall, as soon as practicable after making the determination and in any event within four months beginning with the date of receipt of the application unless the Primary Care Trust has good cause to require a longer period, give notice in writing—

- (a) of its decision and the reasons for that decision to—
 - (i) the applicant,
 - (ii) the Local Pharmaceutical Committee,
 - (iii) the Local Medical Committee,
 - (iv) any person who is included in a pharmaceutical list and whose interests might, in the opinion of the Primary Care Trust, be significantly affected if the application were granted,
 - (v) any LPS chemist whose interests might, in the opinion of the Primary Care Trust, be significantly affected if the application were granted,
 - (vi) any person (except itself) who is a provider of primary medical services within the area of the Primary Care Trust or whose name is included in the dispensing doctor list of the Primary Care Trust, who might, in the opinion of the Primary Care Trust, be significantly affected if the application were granted,
 - (vii) any other Primary Care Trust or Local Health Board to which notice was sent pursuant to regulation 33(2)(f), (i) or (j), and
 - (viii) any other person who has made representations under the provisions of regulation 33(4) or (5); and
- (b) of the rights of appeal arising under regulation 38 to—
 - (i) the applicant, and
 - (ii) any person who made representations under the provisions of regulation 33(4), other than a Local Pharmaceutical Committee or a Local Medical Committee.

(2) In the case of an application that involves a change of ownership and falls to be dealt with under regulation 8(1), for the period of four months specified in paragraph (1) there shall be substituted the period of 30 days.

(3) Any Primary Care Trust or Local Health Board which is notified under paragraph (1)(a)(vii) shall, as soon as practicable, give notice in writing of the decision and reasons for it to—

- (a) the Local Pharmaceutical Committee for its locality;
- (b) the Local Medical Committee for its locality;
- (c) any person whose name is included in the pharmaceutical list, and whose interests might, in the opinion of that Primary Care Trust or Local Health Board, be significantly affected if the application were granted;
- (d) any LPS chemist whose interests might, in the opinion of that Primary Care Trust, be significantly affected if the application were granted; and
- (e) any person (except itself) who is a provider of primary medical services or whose name is included in the dispensing doctor list who might, in the opinion of that Primary Care Trust or Local Health Board, be significantly affected if the application were granted.

(4) In paragraph (1), “making the determination” includes granting an application subject to conditions, where the applicant has agreed to the imposition of the conditions pursuant to regulation 21(6)(a).

Appeals in connection with determinations in respect of controlled localities etc

38.—(1) This regulation shall not apply to any right of appeal specified—

- (a) in regulation 19(6); or
- (b) in regulation 30.

(2) Where a Primary Care Trust—

- (a) has determined an application or a question raised by an application under regulations 33 to 36;
- (b) has refused to consider an application under those regulations on the ground that it is not satisfied as mentioned in regulation 34(2);
- (c) has determined that it should, or should not, postpone the making or termination of arrangements under regulation 60, as mentioned in regulation 20(2) or 35(6)(b); or
- (d) has refused to consider an application for preliminary consent under regulation 40(1) in accordance with the procedures set out in regulations 33 to 36;
- (e) has determined that—
 - (i) the provisional date shall be extended under regulation 62(8),
 - (ii) the application for outline consent shall be refused under paragraph (13)(a) of that regulation or,
 - (iii) outline consent shall lapse under paragraph (13)(b) of that regulation;
- (f) has determined an application for premises approval for new premises under regulation 64(1);
- (g) has determined an application for premises approval for additional or new premises under regulation 65(1) or (3);
- (h) has determined an application for premises approval in relation to a practice amalgamation under regulation 66(3);
- (i) has refused to grant temporary premises approval under regulation 65(9) or 66(4); or
- (j) has determined whether or not to grant premises approval to relevant premises under regulation 67,

an appeal to the Secretary of State may be made, in accordance with paragraph (5), against that determination or, as the case may be, against that refusal, by any person specified in paragraph (3).

(3) The persons who may make an appeal under this regulation are—

- (a) in the case of an appeal mentioned in paragraph (2)(a), (c), (d), (g), (h) and (j)—
 - (i) the applicant,
 - (ii) any person who—
 - (aa) provides primary medical services within the area of the Primary Care Trust (except itself), or any other Primary Care Trust to which a copy of the application was sent under regulation 33(2)(f), (h) or (i), or
 - (bb) whose name is included in the pharmaceutical list or dispensing doctor list of the Primary Care Trust, or any other Primary Care Trust or Local Health Board to which a copy of the application was sent under regulation 33(2)(f), (h) or (i), or
 - (iii) any person who provides local pharmaceutical services under a pharmacy pilot scheme entered into by the Primary Care Trust or any other Primary Care Trust to which a copy of the application was sent under regulation 33(2)(f),but in the case of a person specified in paragraph (ii) or (iii), that person may make an appeal only if he has made representations pursuant to regulation 33(4) in connection with the application; and
- (b) in the case of an appeal mentioned in paragraph (2)(b), (e), (f) and (i), the applicant.

(4) Where, in determining any application or question raised by an application, a Primary Care Trust has, pursuant to regulation 36(9), considered that application or question together with one or more other applications or questions, any of the applicants and any of the persons mentioned in paragraph (3)(a) may appeal against the determination of any of the applications, or against any determination of a question raised by an application, and where the Secretary of State receives appeals against two or more of the determinations, those appeals shall be considered together.

(5) An appeal shall be made in writing within 30 days from the date on which notice of the decision was sent to the appellant and shall contain a concise statement of the grounds of appeal on which the appellant intends to rely.

(6) If the Secretary of State, after considering the notice of appeal, is of the opinion that it discloses no reasonable grounds of appeal, or that the appeal is otherwise vexatious or frivolous, he may determine the appeal by dismissing it.

(7) Unless paragraph (6) applies, the Secretary of State shall send a copy of the notice of appeal to the Primary Care Trust whose determination is appealed against, to those persons mentioned in paragraph (3)(a) and to any Local Medical Committee and Local Pharmaceutical Committee to which a copy of the application was required to be sent under regulation 33(2) or (3).

(8) Any person to whom a copy of the notice of appeal is sent pursuant to paragraph (7) may, within 30 days from the date the copy was sent to him, make representations in writing on the appeal to the Secretary of State.

(9) The Secretary of State may require an oral hearing of an appeal before he determines it.

(10) The Secretary of State shall, where he requires an oral hearing, appoint one or more persons to hear the appeal who shall report to him on it with recommendations as to the relevant findings of fact and their conclusions.

(11) The procedure at any oral hearing shall be determined by the person or persons hearing the appeal.

(12) An oral hearing shall take place at such time and place as the Secretary of State may direct, and notice of the hearing shall be sent, not less than 14 days before the date fixed for the hearing, to—

- (a) the appellant;
- (b) the Primary Care Trust;
- (c) the Local Medical Committee;
- (d) the Local Pharmaceutical Committee; and
- (e) any other person who made representations to the Primary Care Trust in connection with the application.

(13) The appellant and any of the persons to whom notice of the hearing is required to be sent under paragraph (12) may attend and be heard in person or by counsel, solicitor or other representative, and the Primary Care Trust may be represented at the hearing by any duly authorised officer or member, or by counsel or solicitor.

(14) On an appeal under this regulation, the Secretary of State—

- (a) may allow the appeal;
- (b) may, in a case where the Primary Care Trust, on determining the application, considered the question whether to impose conditions to postpone the making or termination of arrangements under regulation 60 (or equivalent provision under the GMS Regulations or PMS Regulations) for the provision by a doctor or GMS contractor or PMS contractor of pharmaceutical services or dispensing services to patients on the relevant patient list, himself impose conditions to postpone for such period as he thinks fit, the making or termination of such arrangements;
- (c) shall, in a case where that question was not considered by the Primary Care Trust when it determined the application, remit the question to the Primary Care Trust for determination;
- (d) shall, where he allows an appeal against a refusal of the Primary Care Trust as mentioned in paragraph (2)(b), remit the application to the Primary Care Trust and direct that regulation 34(1) shall not apply; or
- (e) may dismiss the appeal.

(15) The decision of the Secretary of State shall be given in writing and shall—

- (a) include a statement of his reasons for the decision and of his findings of fact; and

- (b) as soon as practicable, be sent to the persons mentioned in paragraph (12).

Procedure after grant of application

39.—(1) Subject to regulation 21(8), a Primary Care Trust shall not include an applicant in its pharmaceutical list, or include him in respect of different premises or services, before—

- (a) the date specified in paragraph (10); and
- (b) the satisfaction of the condition specified in paragraph (2).

(2) Where an application is granted by the Primary Care Trust (or, on appeal, by the Secretary of State or the FHSAA), the applicant shall be included in the Primary Care Trust's pharmaceutical list, or included in respect of different premises or services, only if, not less than 14 days before—

- (a) the expiry of six months after the date on which the grant was notified to him by the Primary Care Trust in accordance with regulation 27(1) or regulation 37(1); or
- (b) the expiry of such further period or periods, not in all exceeding nine months from the date of notification of the grant, as it, or on appeal the Secretary of State, may for good cause allow,

he notifies the Primary Care Trust, in the form set out in Part 2 of Schedule 4, that he will within the next 14 days commence the provision of the services in respect of which the application was made at the premises to which the application related.

(3) The Primary Care Trust may give written notice to an applicant whose application under regulation 5(1)(a) has been granted requiring him to commence the provision of pharmaceutical services by a date specified in its notice.

(4) The Primary Care Trust may not specify in the notice to be given under paragraph (3) a date—

- (a) earlier than the date specified in paragraph (10);
- (b) subject to sub-paragraph (d), within the period of 28 days beginning with the date of its notice;
- (c) subject to sub-paragraph (d) ending later than the period of 3 months beginning with the date of its notice; or
- (d) ending later than nine months from the date of notification of the grant.

(5) A notice under paragraph (3) shall inform the applicant of his right to appeal against the notice under regulation 29(5) and shall tell him how to make such an appeal.

(6) Where the Primary Care Trust has given a notice under paragraph (3), it shall include the applicant in its pharmaceutical list from the date specified unless the Primary Care Trust—

- (a) the Primary Care Trust for good cause determines that the applicant shall commence the provision of pharmaceutical services from a different date (being a date not later than nine months from the date of notification of the grant), in which case the applicant shall be included in the pharmaceutical list from that date;
- (b) the Primary Care Trust withdraws its notice;
- (c) the applicant appeals under regulation 29(5), in which case where the appeal is unsuccessful the applicant shall be included in the Primary Care Trust's pharmaceutical list in accordance with the Secretary of State's determination of the appeal.

(7) Where—

- (a) the Primary Care Trust has granted an application made under regulation 5(1)(b) or (c); and
- (b) the applicant is suspended from the Primary Care Trust's pharmaceutical list,

before giving the notification required under paragraph (2), a temporary chemist whose application to provide pharmaceutical services in his place has been granted may give that notification in accordance with paragraph (2); and (on satisfaction of the requirements in

paragraph (1)) the Primary Care Trust shall include the temporary chemist in its pharmaceutical list.

(8) Where, at any time after making the application, but before—

- (a) the expiry of the six months referred to in paragraph (2), or of any further period allowed by the Primary Care Trust or, on appeal, by the Secretary of State, in accordance with that paragraph; or
- (b) the date specified by the Primary Care Trust in its notice under paragraph (3),

the applicant notifies the Primary Care Trust that he intends to change within the neighbourhood the premises from which he intends to provide pharmaceutical services, being the same services as those named in the application, and the Primary Care Trust is satisfied that the change is a minor relocation, it may, subject to regulations 25 and 26, amend the premises named in the original application.

(9) The date specified in paragraph (10) is—

- (a) the date before which an applicant may not be included in the pharmaceutical list (or included in respect of different premises or services) for the purposes of paragraph (1); and
- (b) the date of the notification of a grant of an application for the purposes of paragraphs (2) and (4).

(10) The date referred to in paragraph (9) is whichever of the dates mentioned in sub-paragraphs (a) or (b) is the later—

- (a) the day after the expiry of the period of 30 days beginning on the date on which notice of the Primary Care Trust's decision is given under regulation 27(1) or (as the case may be) regulation 37(1); or
- (b) where an appeal or appeals relating to an application are made under these Regulations, the date on which the Secretary of State or the FHSAA, as the case may be, gives notice of his decision or its decision on the last such appeal to be decided.

(11) Where an application is one which falls to be determined in accordance with regulation 22(3), the Primary Care Trust shall not include the applicant in the relevant pharmaceutical list or alter such a list unless the application is finally granted within the meaning of paragraph (14).

(12) In the case of a grant of an application under regulation 5(1)(c), the Primary Care Trust shall within the period of 14 days beginning with the date of receipt of the notice set out in Part 2 of Schedule 4 notify the Primary Care Trust in whose list the applicant's existing premises are located of the applicant's intention to commence the provision of pharmaceutical services from his new premises.

(13) Where—

- (a) an application made by a temporary chemist under regulation 5(1)(b) has been granted;
- (b) the temporary chemist is included in the pharmaceutical list in respect of the premises or services specified in the application; and
- (c) the suspension of the suspended chemist in whose place the temporary chemist is providing pharmaceutical services is terminated (and has not been followed by removal of the suspended chemist's name from the pharmaceutical list),

the temporary chemist's name shall be removed from the pharmaceutical list in respect of the premises or services in question, and the name of the chemist who had previously been suspended shall be included in the pharmaceutical list in respect of those premises or services in the place of the temporary chemist.

(14) An application granted in accordance with the provisions of regulations 33 to 36 shall not be treated as finally granted for the purposes of these Regulations until the end of the period for bringing an appeal under regulation 38 or until the determination of any such appeal, whichever is the later, and "final grant" shall be construed accordingly.

Preliminary consent to be included in a pharmaceutical list

40.—(1) A person to whom regulation 5(1) applies may apply to a Primary Care Trust for consent (in these Regulations referred to as “preliminary consent”).

(2) An application for preliminary consent shall be in writing and shall—

- (a) specify the premises or the location of the premises from which the applicant intends to provide pharmaceutical services if his application is granted;
- (b) specify the pharmaceutical services which it is proposed to provide; and
- (c) provide the information set out in Parts 1 and 3 of Schedule 4.

(3) An application for preliminary consent shall be determined as if it were an application made under regulation 5(1).

(4) A preliminary consent shall have effect for a period of six months from its final grant.

(5) In this regulation and in regulation 41, an application for preliminary consent shall not be treated as finally granted until the end of the period for bringing an appeal relating to that application under any provision of these Regulations or until the determination of any such appeal, whichever is the later, and “final grant” shall be construed accordingly.

Effect of preliminary consent

41.—(1) Subject to paragraph (2) and regulations 19, 25 and 26, where the applicant has been finally granted preliminary consent, the Primary Care Trust shall grant an application made under regulation 5(1) provided that—

- (a) the date of the application under regulation 5(1), being the date on which the application was received by the Primary Care Trust, falls within the period referred to in regulation 40(4);
- (b) the pharmaceutical services which it is proposed to provide are the same as those specified in the application for preliminary consent; and
- (c) the premises specified in the application are within the location in respect of which the preliminary consent was granted.

(2) Where sub-paragraphs (a) and (b) of paragraph (1) are satisfied, but the premises specified in the application are in a different location from that in respect of which preliminary consent was granted, the Primary Care Trust shall treat the application as though it were an application under regulation 5(1)(b)(ii) to change the location of the premises, and the determination of such an application shall be subject to regulations 19, 21, 25 and 26.

(3) The grant of an application under this regulation shall be subject to any conditions imposed under regulation 20, 21, 29, 30 or 38 in relation to the final grant of the corresponding preliminary consent, except where different conditions are imposed under regulation 42 or 43 in relation to the application in which case it shall be subject to those different conditions.

PART 3

Conditional inclusion, suspension and removal from pharmaceutical lists

Review of decision to impose conditions

42.—(1) Where a Primary Care Trust has made a decision to impose conditions in accordance with regulation 21, it may review such a decision, either of its own volition or at the request of the person whose application has been granted subject to conditions.

(2) A person whose application has been granted subject to conditions may not request a review of a Primary Care Trust’s decision until the expiry of a three month period beginning with the date the Primary Care Trust—

- (a) includes his name on its pharmaceutical list; or

(b) grants him preliminary consent,
as the case may be.

(3) A Primary Care Trust must afford to the person whose application has been granted subject to conditions an opportunity to make written representations to the Primary Care Trust or to put his case at an oral hearing before the Primary Care Trust, and it must take the representations into account, or hold the hearing, as the case may be, before reaching its decision upon review.

(4) Upon review, the Primary Care Trust may vary the conditions, impose different conditions or, where the chemist has breached a condition, remove him from its pharmaceutical list.

(5) A Primary Care Trust shall inform the chemist of its decision upon review, the reasons for it (including any facts relied upon), and his right of appeal to the FHSAA.

(6) After a review has taken place at his request, the person whose application has been granted subject to conditions cannot request another review before the expiry of six months from the date of the decision on the previous review.

Appeals following a review

43. A person whose application has been granted subject to conditions under regulation 21(2) may appeal to the FHSAA against any decision of the Primary Care Trust under regulation 42—

- (a) to vary a condition;
- (b) to vary his terms of service; or
- (c) on any review of an earlier such decision of the Primary Care Trust,

and the appeal shall be by way of redetermination of the Primary Care Trust's decision.

Removal for breach of conditions

44. If a chemist fails to comply with a condition which has been imposed under regulation 21, 30, 42 or 43, the Primary Care Trust may remove him from its pharmaceutical list, in accordance with regulation 48.

Removal from pharmaceutical lists

45.—(1) This regulation does not apply to any case to which regulation 44 or 48 applies.

(2) Where a Primary Care Trust determines that a person included in its pharmaceutical list—

- (a) has died; or
- (b) is no longer a chemist,

the Primary Care Trust shall, subject to paragraph (4), remove his name from that list.

(3) Where a chemist provides local pharmaceutical services under a pharmacy pilot scheme, and no longer provides pharmaceutical services, the Primary Care Trust shall remove his name from its pharmaceutical list.

(4) The name of any pharmacist whose business is carried on by representatives in accordance with the provisions of section 72 of the Medicines Act 1968 shall not be removed from the pharmaceutical list under paragraph (2) so long as the business is carried on by them in accordance with the provisions of that Act, and the representatives agree to be bound by the terms of service.

(5) Where a Primary Care Trust receives a notice under regulation 39(12), it shall remove the name of the chemist from its pharmaceutical list in respect of the existing premises with immediate effect from the date specified in the notice as the date for commencing the provision of pharmaceutical services from the new premises.

(6) Where a chemist who had been suspended has resumed the provision of pharmaceutical services from premises other than those from which he had provided services prior to his

suspension, the Primary Care Trust shall remove his name from its pharmaceutical list in respect of the premises from which he no longer provides pharmaceutical services.

(7) Where a Primary Care Trust determines that a chemist, whose name has been included for the preceding six months in a pharmaceutical list, has not during that period provided pharmaceutical services at particular premises, it may remove the chemist's name from the list in respect of those premises.

(8) Where a Primary Care Trust determines that a chemist has breached a condition imposed by—

- (a) regulation 13(2)(a), it shall, subject to regulation 13(2)(b), remove that chemist from the list in respect of the premises to which that condition relates; or
- (b) regulation 13(4), it shall remove that chemist from the list in respect of the premises to which that condition relates.

(9) A period during which the chemist provided no pharmaceutical services by reason only that he was suspended from the pharmaceutical list does not count towards the period of six months referred to in paragraph (7).

(10) Before making any determination under paragraph (7) or (8), the Primary Care Trust shall—

- (a) give the chemist 28 days' notice of its intention;
- (b) afford the chemist an opportunity of making representations to the Primary Care Trust in writing or, if he so desires, in person; and
- (c) consult the Local Pharmaceutical Committee.

(11) Where under paragraph (7) or (8) the Primary Care Trust decides to remove a chemist's name from its pharmaceutical list, it shall give notice in writing of its decision to the chemist.

(12) A chemist to whom a notice has been given under paragraph (11) may, within 30 days of receiving the notice, appeal to the Secretary of State against the decision of the Primary Care Trust and the Primary Care Trust shall not remove the chemist's name from the pharmaceutical list until—

- (a) if no appeal is made, the expiration of that period of 30 days; or
- (b) if an appeal is made, the appeal is determined.

(13) An appeal under paragraph (12) shall be in writing and shall set out the grounds of appeal.

(14) Where the Secretary of State allows the appeal, he shall direct the Primary Care Trust not to remove the chemist's name from the pharmaceutical list.

(15) Nothing in this regulation shall—

- (a) prejudice the right of a chemist to be included again in a pharmaceutical list; or
- (b) affect a chemist who is performing a period of relevant service within the meaning of paragraph (16), and no removal under paragraph (7) shall be effected in respect of any such chemist until six months after he has completed that service.

(16) In paragraph (15), "relevant service" means—

- (a) whole-time service in the armed forces of the Crown in a national emergency, whether as a volunteer or otherwise;
- (b) compulsory whole-time service in those forces, including service resulting from any reserve liability; or
- (c) any equivalent service by a person liable for compulsory whole-time service in those forces.

Criteria for decisions on removal

46.—(1) Where a Primary Care Trust is considering removal of a chemist's name from its pharmaceutical list under section 49F(4)(a) of the Act (an unsuitability case), it shall—

- (a) consider the information from the chemist supplied under paragraphs 29 and 30 of Schedule 1 or paragraphs 16 and 17 of Schedule 3,
- (b) consider any information held by the Secretary of State as to any record about past or current investigations or proceedings involving him or related to him; and
- (c) in reaching its decision take into consideration the matters set out in paragraph (2).

(2) The matters referred to in paragraph (1) are—

- (a) the nature of any offence, investigation or incident;
- (b) the length of time since any such offence, incident, conviction or investigation;
- (c) whether there are other offences, incidents or investigations to be considered;
- (d) the penalty imposed by any licensing or regulatory body, the police or the courts as a result of any such offence, incident or investigation;
- (e) the relevance of any offence, investigation or incident to the provision by the chemist of pharmaceutical services and any likely risk to users of pharmaceutical services or to public finances;
- (f) whether any offence was a sexual offence to which Part 1 of the Sexual Offences Act 2003 applies, or if it had been committed in England and Wales, would have applied;
- (g) whether the chemist (and where the chemist is a body corporate, any director or superintendent of the chemist) has been refused admittance to, conditionally included in, removed, contingently removed or is currently suspended from, any list or any equivalent list, on fitness to practise grounds, and if so, the facts relating to the matter which led to such action and the reasons given by the Primary Care Trust or equivalent body for such action;
- (h) whether the chemist (and where the chemist is a body corporate, any director or superintendent of the chemist) was a director or superintendent, at the time of the originating events, of a body corporate which has been refused admittance to, conditionally included in, removed or contingently removed from, any of a Primary Care Trust's lists or from equivalent lists, on fitness to practise grounds and if so, the facts relating to the matter which led to such action and the reasons given by the Primary Care Trust or equivalent body for such action; and
- (i) whether the chemist (and where the chemist is a body corporate, any director or superintendent of the chemist) was a director or superintendent, at the time of the originating events, of a body corporate which is currently suspended from any of a Primary Care Trust's lists or from equivalent lists, and if so, the facts relating to the matter which led to the suspension and the reasons given by the Primary Care Trust or equivalent body for the suspension.

(3) Where a Primary Care Trust is considering removal of a chemist's name from its pharmaceutical list under section 49F(3) of the Act (a fraud case), it shall consider—

- (a) any information from the chemist supplied under paragraphs 29 and 30 of Schedule 1 or 16 and 17 of Schedule 3;
- (b) any information held by the Secretary of State as to any record about past or current investigations or proceedings involving or related to the chemist; and
- (c) the matters set out in paragraph (4).

(4) The matters referred to in paragraph (3)(c) are—

- (a) the nature of the incidents of fraud;

(a) Section 49F was inserted by the 2001 Act, section 25 and amended by the 2002 Act, section 2(5) and Schedule 2, Part 1, paragraphs 1 and 21 and by the 2003 Act, section 196 and Schedule 14, Part 4.

- (b) the length of time since the last incident of fraud occurred, and since any investigation into that incident of fraud was concluded;
- (c) whether there are other incidents of fraud or other criminal offences to be considered;
- (d) any action taken by any licensing or regulatory or other body, the police or the courts as a result of any such incident or offence;
- (e) the relevance of any investigation into the incident of fraud to the provision by the chemist of pharmaceutical services, and any likely risk to users of pharmaceutical services or to public finances;
- (f) whether the chemist (and, where the chemist is a body corporate, any director or superintendent of the chemist) has been refused admittance to, conditionally included in, removed, contingently removed or is currently suspended from, any list or equivalent list, on fitness to practise grounds, and if so, the facts relating to the matter which led to such action and the reasons given by the Primary Care Trust or equivalent body for such action;
- (g) whether the chemist (and where the chemist is a body corporate, any director or superintendent of the chemist) was a director or superintendent, at the time of the originating events, of a body corporate which has been refused admittance to, conditionally included in, removed or contingently removed from, any list or equivalent list, on fitness to practise grounds, and if so, the facts relating to the matter which led to such action and the reasons given by the Primary Care Trust or equivalent body for such action; and
- (h) whether the chemist (and, where the chemist is a body corporate, any director or superintendent of the chemist) was a director or superintendent, at the time of the originating events, of a body corporate which is currently suspended from any list or equivalent list, and if so, the facts relating to the matter which led to the suspension and the reasons given by the Primary Care Trust or equivalent body for the suspension.

(5) Where a Primary Care Trust is considering removal of a chemist's name from its pharmaceutical list under section 49F(2) of the Act (an efficiency case), it shall—

- (a) consider the information from the chemist supplied under paragraphs 29 and 30 of Schedule 1 or 16 and 17 of Schedule 3;
- (b) consider any information held by the Secretary of State as to any record about past or current investigations or proceedings involving or related to the chemist; and
- (c) in reaching its decision, take into consideration the matters set out in paragraph (6).

(6) The matters referred to in paragraph (5)(c) are—

- (a) the nature of any incident which was prejudicial to the efficiency of the pharmaceutical services provided by the chemist;
- (b) the length of time since the last such incident occurred, and since any investigation into that incident was concluded;
- (c) any action taken by any licensing, regulatory or other body, the police or the courts as a result of any such incident;
- (d) the nature of any incident and whether there is a likely risk to users of pharmaceutical services;
- (e) whether the chemist has previously failed to supply information, make a declaration or comply with an undertaking required by these Regulations;
- (f) whether the chemist (and, where the chemist is a body corporate, any director or superintendent of the chemist) has been refused admittance to, conditionally included in, removed, contingently removed or is currently suspended from, any list or equivalent list, on fitness to practise grounds, and if so, the facts relating to the matter which led to such action and the reasons given by the Primary Care Trust or equivalent body for such action;

- (g) whether the chemist (and, where the chemist is a body corporate, any director or superintendent of the chemist) was a director or superintendent, at the time of the originating events, of a body corporate which has been refused admittance to, conditionally included in, removed or contingently removed from, any list or equivalent list, on fitness to practise grounds, and if so, the facts relating to the matter which led to such action and the reasons given by the Primary Care Trust or equivalent body for such action; and
- (h) whether the chemist (and, where the chemist is a body corporate, any director or superintendent of the chemist) was a director or superintendent, at the time of the originating events, of a body corporate which is currently suspended from any list or equivalent list, and if so, the facts relating to the matter which led to the suspension and the reasons given by the Primary Care Trust or equivalent body for the suspension.

(7) In making any decision under section 49F of the Act, the Primary Care Trust shall take into account the effect of all relevant incidents and offences relating to the chemist of which it is aware, whichever condition it relies on.

(8) When making a decision on any condition in section 49F of the Act, the Primary Care Trust shall state in its decision on which condition (or conditions) in section 49F of the Act it relies.

Cases where the Primary Care Trust must remove a chemist

47.—(1) Subject to paragraph (2), a Primary Care Trust must remove a chemist's name from its pharmaceutical list where it becomes aware that the chemist (and where the chemist is a body corporate, any director or superintendent of the chemist)—

- (a) has been convicted in the United Kingdom of murder;
- (b) has been convicted in the United Kingdom of a criminal offence which was committed after the date on which these Regulations come into force and has been sentenced to a term of imprisonment of over six months; or
- (c) is subject to a national disqualification.

(2) Where the ground for removal under paragraph (1) is that a director of a body corporate has been convicted of a criminal offence (other than murder), the Primary Care Trust shall notify the body corporate that unless—

- (a) the director concerned ceases to be a director of the body corporate within the period of 28 days commencing with the date of the notice; and
- (b) the body corporate notifies the Primary Care Trust of this fact within that period,

it shall remove the name of the body corporate from its pharmaceutical list under paragraph (1).

(3) The Primary Care Trust shall notify the chemist immediately that his name has been removed from the pharmaceutical list.

Procedure on removal

48.—(1) Where a Primary Care Trust is considering—

- (a) removing a chemist's name from the pharmaceutical list under section 49F (disqualification of practitioners) of the Act (other than in cases specified in regulation 47);
- (b) contingently removing a chemist's name from the pharmaceutical list under section 49G(a) (contingent removal) of the Act;
- (c) removing a chemist's name from the pharmaceutical list for breach of a condition imposed under section 49G of the Act; or

(a) Section 49G was inserted by the 2001 Act, section 25 and amended by the 2002 Act, section 2(5) and Schedule 2, Part I, paragraphs 1 and 21.

- (d) removing a chemist's name from the pharmaceutical list for breach of a condition under regulation 44,

on fitness to practise grounds, it shall follow the procedure set out in this regulation.

(2) Before reaching a decision of the kind mentioned in paragraph (1), the Primary Care Trust shall give the chemist—

- (a) notice in writing of any allegation against him;
- (b) notice of what action the Primary Care Trust is considering and on what grounds;
- (c) the opportunity to make written representations to the Primary Care Trust within the period of 28 days beginning with the date of the notification under sub-paragraph (b); and
- (d) the opportunity to put his case at an oral hearing before the Primary Care Trust, if he so requests within the 28 day period mentioned in sub-paragraph (c).

(3) If the Primary Care Trust receives representations or a request for an oral hearing within the period specified in paragraph (2)(c), it must take the representations into account, or hold the hearing, as the case may be, before reaching its decision.

(4) The Primary Care Trust shall inform the chemist of its decision, the reasons for it (including any facts relied upon), and, if the decision is adverse, that he has a right of appeal to the FHSAA.

(5) Where the Primary Care Trust has decided to impose a contingent removal, it shall also inform the chemist of his right to have the decision reviewed in accordance with section 49L(a) (review of decisions) of the Act.

(6) The Primary Care Trust shall inform the chemist that if he wishes to appeal, he must do so within the period of 28 days beginning with the date on which the Primary Care Trust informs him of its decision, and shall tell him how to proceed with making his appeal.

(7) The Primary Care Trust shall not remove a chemist's name from the pharmaceutical list, or impose a contingent removal, until the determination by the FHSAA of any appeal against the Primary Care Trust's decision or any time for appeal has expired.

(8) Where a Primary Care Trust is notified by the FHSAA that it has considered—

- (a) an appeal by a chemist against a contingent removal by the Primary Care Trust, and the FHSAA has decided to remove him instead; or
- (b) an appeal by a chemist under regulation 30 where he has been included in a pharmaceutical list pursuant to regulation 21(8), and the FHSAA has decided not to include him in that list,

the Primary Care Trust shall remove the chemist from its list and shall notify the chemist immediately that it has done so.

Supplementary matters relating to removal

49. In addition to the services covered by the definition of "health scheme" in section 49F(8) (disqualification of practitioners) of the Act, the following shall also be health schemes—

- (a) health services, including medical and surgical treatment, provided by Her Majesty's Forces;
- (b) services provided by Port Health Authorities constituted under the Public Health (Control of Disease) Act 1984(b);
- (c) health services provided to a prisoner in the care of the medical officer or any other officer of a prison appointed for the purposes of section 7 (prison officers) of the Prison Act 1952(c); and

(a) Section 49L was inserted by the 2001 Act, section 25 and amended by the 2002 Act, section 2(5) and Schedule 2, Part I, paragraphs 1 and 23.
(b) 1984 c.22.
(c) 1952 c.52.

- (d) publicly-funded health services provided by or on behalf of any organisation anywhere in the world.

Procedure on suspension

50.—(1) Before reaching a decision to suspend a chemist under section 49I(a) (suspension) or 49J(b) (suspension pending appeal) of the Act, the Primary Care Trust shall give the chemist—

- (a) notice in writing of any allegation against him;
- (b) notice of what action the Primary Care Trust is considering and on what grounds;
- (c) the opportunity to make written representations to the Primary Care Trust within the period of 28 days beginning with the date of the notification under sub-paragraph (b); and
- (d) the opportunity to put his case at an oral hearing before the Primary Care Trust, if he so requests within the 28 day period mentioned in sub-paragraph (c).

(2) If the Primary Care Trust receives representations or a request for an oral hearing within the period specified in paragraph (1)(c), it must take the representations into account, or hold the hearing, as the case may be, before reaching its decision.

(3) The Primary Care Trust may suspend a chemist with immediate effect once it has reached a decision to suspend him.

(4) The Primary Care Trust shall inform the chemist of its decision and the reasons for it (including any facts relied upon).

(5) Where the Primary Care Trust has decided to suspend a chemist under section 49I (suspension) of the Act, it shall also inform the chemist of his right to have the decision reviewed in accordance with section 49L (review of decisions) of the Act.

Procedure on review of Primary Care Trust decision

51.—(1) Where, in accordance with section 49L (review of decisions) of the Act, a Primary Care Trust must review its decision to contingently remove a chemist from the pharmaceutical list or suspend a chemist from the pharmaceutical list under section 49I (suspension) of the Act, or where it decides to review such a decision, it shall give the chemist—

- (a) notice in writing that it intends to review its decision;
- (b) notice of the decision it is minded to take upon review, and the reasons for it;
- (c) the opportunity to make written representations to the Primary Care Trust within the period of 28 days beginning with the date of the notification under sub-paragraph (a); and
- (d) the opportunity to put his case at an oral hearing before the Primary Care Trust, if he so requests within the 28 day period mentioned in sub-paragraph (c).

(2) If the Primary Care Trust receives representations or a request for an oral hearing within the period specified in paragraph (1)(c), it must take the representations into account, or hold the hearing, as the case may be, before reaching its decision.

(3) The Primary Care Trust shall inform the chemist of its decision, the reasons for it (including any facts relied upon), and any right of appeal to the FHSAA.

(4) The Primary Care Trust shall inform the chemist that if he wishes to exercise a right of appeal, he must do so within the period of 28 days beginning with the date on which the Primary Care Trust informs him of its decision, and shall tell him how to proceed with making his appeal.

(5) The Primary Care Trust shall also notify the chemist of his right to have the decision further reviewed in accordance with section 49L of the Act.

(a) Section 49I was inserted by the 2001 Act, section 25 and amended by the 2002 Act, section 2(5) and Schedule 2, Part I, paragraphs 1 and 21.
(b) Section 49J was inserted by the 2001 Act, section 25 and amended by the 2002 Act, section 2(5) and Schedule 2, Part I, paragraphs 1 and 22.

Review periods on national disqualification

52. The period for review of a national disqualification shall be the period specified below instead of that in section 49N(8)(a) (national disqualification) of the Act where the circumstances are that—

- (a) on making a decision to impose a national disqualification, the FHSAA states that it is of the opinion that the criminal or professional conduct of the disqualified person is such that there is no realistic prospect of a further review being successful if held within the period specified in section 49N(8)(a) of the Act, in which case the reference to “two years” in that provision shall be a reference to five years;
- (b) on the last review by the FHSAA of a national disqualification the disqualified person was unsuccessful and the FHSAA states that it is of the opinion that there is no realistic prospect of a further review being successful if held within a period of three years beginning with the date of its decision on that review, in which case the reference to “one year” in section 49N(8)(b) of the Act shall be a reference to three years;
- (c) the FHSAA states that it is of the opinion that because a criminal conviction considered by the FHSAA in reaching its decision has been quashed or the penalty reduced on appeal, there is a need for an immediate review, in which case the reference to “two years” or “one year” in section 49N(8) of the Act shall be a reference to the period that has already elapsed; or
- (d) the FHSAA is of the opinion that because the decision of a licensing or regulatory body has been quashed or the penalty reduced on appeal, there is a need for an immediate review, in which case the reference to “two years” or “one year” in section 49N(8) of the Act shall be a reference to the period that has already elapsed.

Withdrawals from the list

53.—(1) Subject to paragraphs (2) to (4), the Primary Care Trust shall, on receiving any notice from any chemist pursuant to paragraph 35 of Schedule 1 or paragraph 22 of Schedule 3, so amend its pharmaceutical list either—

- (a) on the date notified by him in accordance with paragraph 35 of Schedule 1 or paragraph 22 of Schedule 3; or
- (b) on the date from which it has agreed that the withdrawal shall take effect,

whichever is the earlier.

(2) Where a Primary Care Trust is investigating a chemist—

- (a) for the purpose of deciding whether or not to exercise its powers under section 49F (disqualification of practitioners), 49G (contingent removal) or 49I (suspension) of the Act;
- (b) in order to see whether the chemist has failed to comply with a condition imposed on his inclusion under regulation 21, 30, 42 or 43 so as to justify his removal from the pharmaceutical list; or
- (c) who has been suspended under section 49I(1)(a) of the Act,

the chemist may not withdraw from any lists in which he is included, except where the Secretary of State has given his consent, until the matter has been finally determined by the Primary Care Trust.

(3) A chemist may withdraw a notice given pursuant to paragraph 35 of Schedule 1 or paragraph 22 of Schedule 3 at any time before the Primary Care Trust removes his name from its pharmaceutical list.

(a) Section 49N was inserted by the 2001 Act, section 25 and amended by the 2002 Act, section 2(5) and Schedule 2, Part I, paragraphs 1 and 25 and by the 2003 Act, section 184 and Schedule 11, paragraphs 7 and 24.

(4) Where a Primary Care Trust has decided to remove a chemist from its pharmaceutical list under section 49F or 49G of the Act, or contingently remove him under section 49G of the Act, or remove him for breach of a condition imposed on inclusion under regulation 44, but has not yet given effect to its decision, the chemist may not withdraw from any list in which he is included, except where the Secretary of State has given his consent.

(5) Where a Primary Care Trust has suspended a chemist under section 49I(1)(b) of the Act, the chemist may not withdraw from any of a Primary Care Trust's lists in which he is included, except where the Secretary of State has given his consent, until the decision of the relevant court or body is known and the matter has been considered and finally determined by the Primary Care Trust.

Temporary provision of services during a period of suspension

54.—(1) A chemist who has been suspended, except a temporary chemist who has been suspended, may nominate to the Primary Care Trust a person or persons to provide pharmaceutical services in his place, for the period of his suspension.

(2) A nominated person may apply to the Primary Care Trust, in accordance with this regulation—

- (a) for temporary inclusion in that Primary Care Trust's pharmaceutical list; or
- (b) if he is already included in that Primary Care Trust's pharmaceutical list, for temporary inclusion in respect of the premises from which the suspended chemist had undertaken to provide pharmaceutical services, or in respect of the pharmaceutical services which the suspended chemist had undertaken to provide.

(3) An application shall be in writing and shall include—

- (a) the name and address of the applicant and the suspended chemist;
- (b) a statement as to whether the applicant is a registered pharmacist, a person lawfully conducting a retail pharmacy business in accordance with section 69 (general provisions) of the Medicines Act 1968(a), or a supplier of appliances;
- (c) the address of the premises from which the applicant undertakes to provide pharmaceutical services;
- (d) a statement to the effect that the applicant is applying to provide pharmaceutical services from the specified premises, only for the period of the suspended chemist's suspension and for so long as the suspended chemist consents; and
- (e) the information and undertakings specified in Part 3 of Schedule 4.

(4) Where the applicant is not already on the Primary Care Trust's pharmaceutical list, the Primary Care Trust shall grant the application, subject to paragraphs (6), (7), (8), (10), (11) and (15) and regulations 19, 21 and 26.

(5) Where the applicant is already on the Primary Care Trust's pharmaceutical list, the Primary Care Trust shall grant the application, subject to paragraphs (10), (11) and (15) and regulation 26.

(6) An application made under this regulation by a person who qualified to have his name registered under the Pharmacy Act 1954(b) by virtue of section 4A(c) (qualification by appropriate European diploma for registration) of that Act shall not be granted unless the applicant satisfies the Primary Care Trust that he has the knowledge of English which, in the interests of himself and persons making use of the services to which the application relates, is necessary for the provision of pharmaceutical services in the Primary Care Trust's area.

(7) Subject to paragraph (8), an application to a Primary Care Trust in whose pharmaceutical list the applicant is not already included shall not be granted unless the Primary Care Trust has—

(a) 1968 c.67.

(b) 1954 c.61.

(c) Section 4A was inserted by S.I. 1987/2202, article 2(4), and amended by S.I. 1996/1405, regulation 2, S.I. 2003/3148, regulation 8 and S.I. 2004/1947, regulation 13.

- (a) checked as far as practicable the references and information provided by the applicant in accordance with Part 3 of Schedule 4;
- (b) checked with the National Health Service Counter Fraud and Security Management Service whether the applicant (and where the applicant is a body corporate, any director or superintendent of the applicant) has any record of a fraud case; and
- (c) considered whether there are grounds—
 - (i) for refusing the application under regulation 19, or
 - (ii) for imposing conditions in accordance with regulation 21.

(8) Where a person is urgently needed as a temporary chemist in order to secure the adequate provision of pharmaceutical services in the neighbourhood in which the premises from which the applicant intends to provide pharmaceutical services are located, and it is not practicable for the Primary Care Trust to comply with paragraph (7) before granting his application, the Primary Care Trust may grant his application, provided that it complies with paragraph (7) as soon as practicable after that grant.

(9) For the purpose of determining the adequacy of the provision of pharmaceutical services pursuant to paragraph (8), a Primary Care Trust shall treat any local pharmaceutical services being provided in the neighbourhood in which the premises named in the application are located as if they were pharmaceutical services, and shall not take into account any pharmaceutical services provided by a distance selling chemist in that neighbourhood.

(10) A Primary Care Trust must refuse an application if—

- (a) the suspended chemist is a body corporate and the applicant—
 - (i) is an employee of the body corporate,
 - (ii) is, or was at the time a suspension was imposed, or at the time of the originating events, a director or superintendent of the suspended chemist,
 - (iii) is a body corporate in which—
 - (aa) the suspended chemist; or
 - (bb) any person who is, or was at the time a suspension was imposed, or at the time of the originating events, a director or superintendent of the suspended chemist,
 is a majority shareholder,
 - (iv) is a body corporate which has a director or superintendent who is an employee of the suspended chemist, or
 - (v) is a body corporate which has a director or superintendent who is, or was at the time a suspension was imposed, or was at the time of the originating events, a director or superintendent of the suspended chemist; or
- (b) the suspended chemist is an individual and the applicant—
 - (i) is an employee of the suspended chemist, or
 - (ii) is a body corporate, of which the suspended chemist or his employee is a director or superintendent or the majority shareholder.

(11) A Primary Care Trust may refuse an application if—

- (a) the suspended chemist is a body corporate and the applicant (or where the applicant is a body corporate, any director or superintendent of the applicant) is in a relationship (including a family relationship) with the suspended chemist, or with any person who is, or was at the time a suspension was imposed, or was at the time of the originating events, a director or superintendent of the suspended chemist, the nature of which makes it unlikely that the applicant will be able to exercise an appropriate degree of autonomy; or
- (b) the suspended chemist is an individual and the applicant (or where the applicant is a body corporate, any director or superintendent of the applicant) is in a relationship (including a family relationship) with the suspended chemist, the nature of which makes it unlikely that the applicant will be able to exercise an appropriate degree of autonomy.

(12) Where a Primary Care Trust receives an application to which it considers that paragraph (11) applies—

- (a) before determining the application, it shall invite the applicant and the suspended chemist to make representations to it in writing or, if they so desire, in person, before the end of the period of 14 days beginning on the day on which the Primary Care Trust invited representations; and
- (b) it shall make a decision on the application before the end of the period of 14 days beginning on the day on which it receives or hears the applicant's or the suspended chemist's representations, whichever is the later of the two, or, where no representations are made, the day on which the time for making such representations expires.

(13) Before the end of the period of 14 days beginning with the day on which it has received both a nomination under paragraph (1) and an application under paragraph (2), a Primary Care Trust shall—

- (a) determine the application;
- (b) where it considers that paragraph (11) applies, invite representations in accordance with paragraph (12)(a); or
- (c) where it considers that there are grounds for deferring consideration or determination of the application under regulation 26, notify the applicant in writing to that effect.

(14) A Primary Care Trust shall, as soon as is practicable, give notice in writing of its decision on an application to—

- (a) the applicant;
- (b) the suspended chemist; and
- (c) where it decides to grant the application, the Local Pharmaceutical Committee and the Local Medical Committee established for the Primary Care Trust's area.

(15) Where an applicant is already included in the Primary Care Trust's pharmaceutical list, or has been granted preliminary consent to be included in that list, and in either case is subject to conditions imposed in accordance with regulations 21, 30, 42 or 43, a grant of his application under this regulation shall be subject to those same conditions.

(16) Where a Primary Care Trust grants an application under this regulation, it shall include the applicant in its pharmaceutical list or, where the applicant is already included in that list, include him in relation to the premises or services specified in the application.

(17) The suspended chemist may at any time during the period of his suspension notify the Primary Care Trust in writing that—

- (a) he no longer consents to the provision of pharmaceutical services by the temporary chemist; and
- (b) he requires that the temporary chemist should cease the provision of pharmaceutical services with effect from a specified date.

(18) A suspended chemist must give the Primary Care Trust at least two working days' notice of the date specified in paragraph (17)(b); and in this paragraph, "working day" means any day other than Saturday, Sunday, Christmas Day, Good Friday or a bank holiday.

(19) Where the Primary Care Trust receives notification from the suspended chemist in accordance with paragraphs (17) and (18), it shall, as soon as practicable, notify the temporary chemist in writing that he is to cease the provision of pharmaceutical services with effect from the specified date, and shall remove his name from the pharmaceutical list with effect from that date.

(20) Subject to paragraph (21), a Primary Care Trust may at any time remove a temporary chemist's name from the pharmaceutical list if the temporary chemist is in a relationship with the suspended chemist which makes it unlikely that he will be able to exercise an appropriate degree of autonomy.

(21) Where a Primary Care Trust is minded to remove a temporary chemist's name from the pharmaceutical list in accordance with paragraph (20), it shall—

- (a) as soon as practicable, notify the suspended chemist and the temporary chemist that it is so minded, giving a brief statement of its reasons;
- (b) afford to the suspended chemist and the temporary chemist an opportunity to make representations to it in writing or, if they so desire, in person, before the end of the period of 14 days beginning on the day on which the notification is given;
- (c) make a decision as to removal from the pharmaceutical list before the end of the period of 14 days beginning on the day on which it receives or hears the applicant's or the suspended chemist's representations, whichever is the later of the two, or, where no representations are made, the day on which the time for making such representations expires; and
- (d) as soon as practicable, give notice in writing of its decision to the suspended chemist and the temporary chemist.

(22) On and after the date on which the period of suspension of the suspended chemist ends (whether the suspended chemist's name is removed from the pharmaceutical list or whether he is reinstated as a chemist), the temporary chemist may no longer provide the pharmaceutical services that he had previously provided in the place of the chemist who had been suspended; and the Primary Care Trust shall remove the temporary chemist's name from its pharmaceutical list with effect from that date.

(23) In this regulation, references to removing a temporary chemist's name from a pharmaceutical list shall be construed as removing his name in respect of the premises from which he has provided pharmaceutical services under this regulation (or in respect of the pharmaceutical services he has provided under this regulation).

(24) Where a Primary Care Trust has refused a person's application to be a temporary chemist that person may appeal to the Secretary of State in accordance with regulation 29.

Notifications

55.—(1) Where a Primary Care Trust—

- (a) removes a chemist's name from the pharmaceutical list under section 49F of the Act;
- (b) contingently removes a chemist's name from the pharmaceutical list under section 49G of the Act;
- (c) suspends a chemist from the pharmaceutical list;
- (d) removes a chemist's name from the pharmaceutical list for breach of a condition under regulation 44; or
- (e) removes a chemist's name from the pharmaceutical list for breach of a condition imposed under section 49G of the Act,

it shall notify the persons and bodies specified in regulation 28(2), and shall additionally notify those specified in regulation 28(3) if so requested by those persons or bodies in writing (including electronically), of the matters set out in regulation 28(4); and the applicant or chemist in relation to whom such a decision has been taken under this paragraph is called a "pharmaceutical practitioner" in that regulation.

(2) Regulation 28(5) to (8) shall apply to notifications given under this regulation as they apply to notifications given under regulation 28(1).

PART 4

Payments to chemists

Standards of, and payments for, drugs and appliances

56.—(1) For the purpose of enabling arrangements to be made for the provision of pharmaceutical services, the Secretary of State shall compile and publish a statement (in these

Regulations referred to as “the Drug Tariff”) which he may amend from time to time and which, subject to paragraph (2), shall include—

- (a) the list of appliances for the time being approved by the Secretary of State for the purposes of section 41 (arrangements for pharmaceutical services) of the Act and, in the case of a restricted availability appliance, the categories of persons for whom or purposes for which the appliance is approved;
- (b) the list of chemical reagents for the time being approved by the Secretary of State for the purposes of section 41 of the Act;
- (c) the list of drugs for the time being approved by the Secretary of State for the purposes of section 41 of the Act;
- (d) the prices on the basis of which the payment for drugs and appliances ordinarily supplied is to be calculated;
- (e) the method of calculating the payment for drugs not mentioned in the Drug Tariff;
- (f) the method of calculating the payment for containers and medicine measures;
- (g) the dispensing or other fees or allowances payable in respect of the provision of pharmaceutical services;
- (h) the dispensing or other fees or allowances payable in respect of the temporary provision of pharmaceutical services under regulation 54;
- (i) arrangements for claiming fees, allowances and other remuneration for the provision of pharmaceutical services; and
- (j) the method by which a claim may be made for compensation for financial loss in respect of oxygen equipment specified in the Drug Tariff.

(2) The Drug Tariff may state in respect of any specified fee or allowance falling within paragraph (1)(g) or (h), or any other specified fee, allowance or other remuneration in respect of the provision of pharmaceutical services by chemists included in the pharmaceutical list of a Primary Care Trust, that the determining authority for that fee, allowance or other remuneration for those chemists is the Primary Care Trust, and in such a case paragraphs (5) and (6) shall apply.

(3) The prices referred to in paragraph (1)(d) may be fixed prices or may be subjected to monthly or other periodical variations to be determined by reference to fluctuations in the cost of drugs and appliances.

(4) A chemist shall supply, in response to a request from the Secretary of State, within 30 days of the notification of the request, any information which the Secretary of State may require for the purpose of conducting any inquiry into the prices, payments, fees, allowances and remuneration specified in paragraph (1)(d) to (i).

(5) The Primary Care Trust shall consult the Local Pharmaceutical Committee before making any determination by virtue of paragraph (2).

(6) A determination made by the Primary Care Trust by virtue of paragraph (2) shall include the arrangements for claiming the specified fees, allowances or other remuneration, and shall be published by the Primary Care Trust in whatever way it thinks suitable for bringing that determination to the attention of the chemists included in its pharmaceutical list.

Claims and overpayments

57.—(1) Any claim for fees, allowances or other remuneration by chemists or doctors shall be made in accordance with the provisions of the Drug Tariff or, as the case may be, in accordance with any arrangements for claiming them included in a determination made by the Primary Care Trust by virtue of regulation 56(2).

(2) Where it considers that a payment has been made to a chemist or doctor in circumstances when it was not due, the Primary Care Trust, except to the extent that the Secretary of State, on the application of the Primary Care Trust, directs otherwise, shall draw the overpayment to the attention of the chemist or the doctor, and—

- (a) where the overpayment is admitted by him; or

- (b) where, in the case of a chemist, the overpayment is not so admitted but, the matter having been referred under regulation 5(1) of the National Health Service (Service Committees and Tribunal) Regulations 1992(a) for investigation, the Primary Care Trust, or the Secretary of State on appeal under regulation 9(1)(c) of those Regulations, decides that there has been an overpayment,

the amount overpaid shall, subject to any determination of the Secretary of State pursuant to regulation 11(1) of the National Health Service (Service Committees and Tribunal) Regulations 1992(b), be recoverable, either by deduction from the remuneration of the doctor or chemist or in some other manner.

(3) Recovery of an overpayment under this regulation shall be without prejudice to the investigation of an alleged breach of the terms of service.

Payments to suspended chemists

58.—(1) The Primary Care Trust shall make payments to any chemist who is suspended in accordance with the Secretary of State’s determination in relation to such payments.

(2) The Secretary of State shall make the determination in accordance with paragraph (3) after consultation with such organisations as he may recognise as representing chemists with whom arrangements for the provision of pharmaceutical services exist, and it shall be published with the Drug Tariff.

(3) The determination may be amended from time to time by the Secretary of State after consultation with the organisations referred to in paragraph (2), and any amendments shall also be published in the Drug Tariff.

(4) The Secretary of State’s determination may include provision that payments in accordance with the determination are not to exceed a specified amount in any specified period.

Reward Scheme

59.—(1) A chemist who is presented with, or receives, an order under paragraph 5(2) or (3) of Schedule 1 or paragraph 4(2) of Schedule 3 shall be eligible to claim a payment from the Primary Care Trust in such manner as is specified in the Drug Tariff if—

- (a) in accordance with paragraph 9 of Schedule 1 or paragraph 7 of Schedule 3 he refused to provide the drugs or listed appliances ordered and informed the Primary Care Trust of this action as soon as practicable; or
- (b) he provided the drugs or listed appliances pursuant to paragraph 5(2) or (3) of Schedule 1 or paragraph 4(2) of Schedule 3 but had reason to believe at that time or subsequently came to have reason to believe that the order was not a genuine order for the person named on the prescription form or repeatable prescription and informed the Primary Care Trust of this belief as soon as practicable,

and in either case he has sent the order referred to in this paragraph (or, in the case of an electronic prescription, details of it) to the Primary Care Trust, and the Primary Care Trust has established that the order referred to in this paragraph was not a genuine order for the person named on the prescription form or repeatable prescription.

(2) The Primary Care Trust shall in respect of any claim under paragraph (1) make such payment as is due to the chemist calculated in the manner specified in the Drug Tariff.

(3) In this paragraph “order” includes a purported order.

(a) S.I. 1992/664. Regulation 5 has been amended by S.I. 1996/703, 2002/2469 and 2004/865.
(b) Regulation 11 has been amended by S.I. 1996/703, 2002/2469 and 2004/865.

PART 5

Provision of Pharmaceutical Services by Doctors

Arrangements for provision of pharmaceutical services by doctors

60.—(1) Where a patient—

- (a) satisfies a Primary Care Trust that he would have serious difficulty in obtaining any necessary drugs or appliances from a pharmacy by reason of distance or inadequacy of means of communication;
- (b) is resident in a controlled locality, at a distance of more than 1.6 kilometres from any pharmacy (other than a distance selling chemist), and one of the conditions specified in paragraph (3) is satisfied in his case;
- (c) is resident in a controlled locality and any pharmacy within a distance of 1.6 kilometres from where the patient lives—
 - (i) has been determined to be in a reserved location, and that determination has not been altered on appeal or by way of a further determination, or
 - (ii) is a distance selling chemist,and one of the conditions specified in paragraph (3) is satisfied in his case; or
- (d) is one to whom sub-paragraph (a) or (b) applies and at the time of the request the patient is living as a member of the household, other than as a temporary resident, of another person in respect of whom a doctor has residual premises approval, and for this purpose “residual premises approval” has the same meaning as in regulation 66(9) and a person is a “temporary resident” if he intends to stay in the household for more than 24 hours but not longer than three months,

he may at any time request in writing a doctor who falls within paragraph (2) to provide him with pharmaceutical services.

(2) A doctor falls within this paragraph if he is—

- (a) the GMS contractor, the PMS contractor or the APMS contractor;
- (b) engaged or employed by the GMS contractor, the PMS contractor or the APMS contractor; or
- (c) engaged by a Primary Care Trust for the purposes of providing primary medical services within a PCTMS practice,

on whose patient list the patient making the request is included.

(3) The conditions referred to in paragraph (1)(b) and (c) are—

- (a) that—
 - (i) there is in effect an outline consent granted to—
 - (aa) that doctor;
 - (bb) another doctor who is a party to the GMS contract, the PMS agreement or the APMS contract concerned;
 - (cc) another doctor who is engaged or employed by the GMS contractor or the PMS contractor or the APMS contractor concerned; or
 - (dd) another doctor who is providing primary medical services within the same PCTMS practice,
 - (ii) there is in effect premises approval in relation to the premises from which the doctor will dispense to that patient, and
 - (iii) any conditions imposed under regulation 20, 29(18)(b), 32(10)(b) or 38(14)(b) in connection with that grant are such as to permit arrangements to be made under this regulation for the provision of pharmaceutical services by that doctor to the patient; or

- (b) that—
 - (i) immediately before these Regulations came into force, arrangements or requirements were in effect under the 1992 Regulations for—
 - (aa) that doctor;
 - (bb) another doctor who is a party to the GMS contract or the PMS agreement concerned;
 - (cc) another doctor who is engaged or employed by the GMS contractor or PMS contractor concerned; or
 - (dd) any previous doctor who was a party to the GMS contract or the PMS agreement concerned, or who was engaged or employed by the GMS contractor or PMS contractor concerned,
 to provide drugs or appliances to patients,
 - (ii) the patient—
 - (aa) has not previously been included in a patient list;
 - (bb) has changed his address from that last notified to the Primary Care Trust; or
 - (cc) has not changed his address but, immediately before his acceptance as a patient by that doctor, was being provided with pharmaceutical services by a doctor pursuant to an arrangement or requirement under the 1992 Regulations, and
 - (iii) there is in effect premises approval in relation to the premises from which the doctor will dispense to that patient.
- (4) If a doctor so requested by a patient under paragraph (1)—
 - (a) applies to provide pharmaceutical services to the patient, and sends with his application the patient's request in writing, the Primary Care Trust shall make arrangements with him for the provision at listed premises of such services by him; or
 - (b) does not so apply within 30 days, the Primary Care Trust may, subject to paragraph (6), require him to undertake such provision at listed premises and shall give him notice in writing to that effect.
- (5) Subject to regulation 66, an arrangement made by a Primary Care Trust under paragraph (4)(a) shall—
 - (a) have effect from the date of the patient's request in writing; and
 - (b) enable—
 - (i) that doctor,
 - (ii) any other doctor who is party to the same GMS contract, PMS agreement or APMS contract as that doctor,
 - (iii) any other doctor who is employed or engaged by the same GMS, PMS or APMS contractor, or
 - (iv) any doctor who provides primary medical services within the same PCTMS practice, to provide pharmaceutical services at listed premises for the patient so long as the arrangement remains in effect.
- (6) A Primary Care Trust shall not under paragraph (4)(b) require a doctor to provide pharmaceutical services at listed premises to a person on the relevant patient list for that doctor if that doctor satisfies the Primary Care Trust, or on appeal, the Secretary of State that—
 - (a) he does not normally provide pharmaceutical services under this regulation; or
 - (b) in the case of a person to whom paragraph (1)(b), (c) or (d) applies, the person would not have serious difficulty, by reason of distance or inadequacy of means of communication, in obtaining drugs and appliances from a pharmacy.
- (7) A Primary Care Trust shall give a doctor reasonable notice—

- (a) that it requires him to provide pharmaceutical services to any person; or
- (b) subject to paragraph (8), that where a person no longer satisfies the provisions of paragraph (1), the doctor shall discontinue the provision of pharmaceutical services to that person.

(8) A notice under paragraph (7)(b)—

- (a) shall be subject to any postponement or termination of arrangements for the provision of pharmaceutical services to that person by that doctor made under regulation 20(2), 29(18)(b), 32(10)(b) or 38(14)(b); and
- (b) shall not be given—
 - (i) pending any appeal against a decision by a Primary Care Trust to postpone the making or termination of such arrangements, or
 - (ii) where regulation 31(9) so requires.

(9) Notwithstanding paragraph (4), where a drug or appliance is one for which a doctor is entitled to an additional payment if he provides it, he may, with the consent of the patient, instead of providing it himself, order it by issuing a prescription to the patient in accordance with paragraph 39 of Schedule 6 to the GMS Regulations (or paragraph 38 of Schedule 5 to the PMS Regulations or equivalent provision applying in relation to an APMS contractor or PCTMS practice).

(10) Where under any provision of regulations revoked by, and not re-enacted in, the 1992 Regulations, an arrangement or requirement for a doctor to provide drugs or appliances to a patient was in effect immediately before the 1992 Regulations came into force, that arrangement or requirement shall have effect as though made under this regulation notwithstanding that neither of the conditions specified in paragraph (3) is satisfied.

(11) A doctor who provides pharmaceutical services to some or all of the patients on the relevant patient list in accordance with this regulation may provide any necessary pharmaceutical services to a person whom the relevant GMS, PMS or APMS contractor or the PCTMS practice has accepted as a temporary resident under paragraph 16 of Schedule 6 to the GMS Regulations or under paragraph 15 of Schedule 5 to the PMS Regulations or any equivalent provision applying to APMS contracts and PCTMS practices.

(12) An appeal under paragraph (6) shall be made in writing within the period of 30 days beginning with the date on which notice of the decision was sent to the doctor and shall contain a concise statement of the grounds of appeal.

(13) The Secretary of State shall, on receipt of any notice of appeal under this regulation, send a copy of that notice to the Primary Care Trust and the relevant GMS contractor, PMS contractor or APMS contractor, and the Primary Care Trust and relevant GMS contractor, PMS contractor or APMS contractor may, within 30 days from the date on which the Secretary of State sent a copy of the notice of appeal, make representations in writing to him.

(14) The Secretary of State may determine an appeal pursuant to paragraph (6) in such manner as he thinks fit.

(15) The Secretary of State shall, upon determination by him of an appeal under this regulation, give notice of his decision in writing, together with the reasons for it, to the appellant, to the Primary Care Trust and to the relevant GMS contractor, PMS contractor or APMS contractor.

Outline consent and premises approval

61.—(1) A doctor wishing to be granted the right to provide pharmaceutical services under regulation 60(1)(b) or (c) by arrangement with a Primary Care Trust to patients residing in an area, may apply to the Primary Care Trust in writing for—

- (a) consent (in these Regulations referred to as “outline consent”) specifying the area in relation to which he wishes the outline consent to be granted; and
- (b) approval of any premises from which he wishes to dispense (“premises approval”), specifying—

- (i) the premises for which he wishes to be granted premises approval and whether those premises are listed premises in relation to a different area, and
- (ii) whether the application arises because there has been a practice amalgamation and, if so, the names of the doctors or contractors participating in the amalgamation.

(2) An application under paragraph (1) shall be determined in accordance with paragraph (3) and regulations 18, 20(2), 33 to 38 and 62.

(3) The Primary Care Trust may refuse an application in respect of some of the premises for which approval is sought (notwithstanding that it would, if determining the application for those premises in isolation, grant it) where the number of applications for premises approval are such, or the circumstances in which they are made are such, that to grant all or some of them would prejudice the proper provision of primary medical services, dispensing services, local pharmaceutical services or pharmaceutical services in any locality.

Taking effect of outline consent and premises approval

62.—(1) When granting outline consent, the Primary Care Trust shall determine in accordance with paragraph (2) when the outline consent is to take effect.

(2) The outline consent shall take effect—

- (a) in relation to premises to which paragraph (3) applies, on the date on which outline consent is finally granted; and
- (b) in relation to premises to which paragraph (4) applies, in accordance with paragraphs (11) to (13).

(3) This paragraph applies to premises for which outline consent is sought and—

- (a) which were, on the date of receipt of the application by the Primary Care Trust—
 - (i) practice premises, or
 - (ii) in a reserved location; or
- (b) in relation to which, on the day before the date on which the application for outline consent is granted, there are no outstanding applications.

(4) This paragraph applies where, on the day before the date on which the application for outline consent is granted, there are outstanding applications.

(5) For the purposes of paragraphs (3) and (4), and regulations 64 and 65, an “outstanding application” means an application under regulation 5 or 40 which—

- (a) is in relation to premises which are within 1.6 kilometres of the premises for which premises approval has been sought; and
- (b) which—
 - (i) has been made but not determined (including on appeal), or
 - (ii) has been granted but the provision of pharmaceutical services from those premises has not commenced.

(6) Where paragraph (2)(b) applies, notification of the determination of the application for outline consent by the Primary Care Trust or, on appeal, by the Secretary of State, shall give details of—

- (a) the outstanding applications; and
- (b) the earliest date on which, subject to paragraph (7), an application can be made under paragraph (11) to the Primary Care Trust for a determination that the outline consent should come into effect (“provisional date”).

(7) The provisional date is the day after the end of a period of one year beginning with the date of—

- (a) the determination of the application for outline consent; or
- (b) where that determination is the subject of an appeal, the determination of that appeal.

(8) The Primary Care Trust may, at any time before the provisional date, for good cause determine that the provisional date shall be extended for a period not exceeding three months beginning with the date specified in paragraph (7)(a) or (b), and any reference in this regulation or in regulation 64 to the provisional date shall include a reference to the provisional date as extended under this paragraph.

(9) The Primary Care Trust shall—

- (a) ensure that any notifications required to be given by the Primary Care Trust or the Secretary of State in relation to any outstanding applications are also given to the doctor who made the application under regulation 61;
- (b) notify that doctor if any outstanding application is withdrawn; and
- (c) where it extends the provisional date under paragraph (8), notify that doctor of the new provisional date.

(10) The outline consent shall lapse if, before the provisional date, pharmaceutical services are provided from premises which were the subject of an outstanding application which has been granted.

(11) On, or as soon as reasonably practicable after, the provisional date, the Primary Care Trust shall notify the doctor who made the application under regulation 61 and—

- (a) he may within three months of the provisional date request the Primary Care Trust in writing to determine whether the outline consent should come into effect; and
- (b) the Primary Care Trust shall determine the request as soon as practicable and in accordance with paragraphs (12) and (13).

(12) Where on the date of the determination under paragraph (11), the premises are practice premises, the Primary Care Trust shall determine that the outline consent and premises approval in respect of those premises shall come into effect on that date.

(13) Where, on the date of the determination under paragraph (11), the premises are not practice premises—

- (a) the application for outline consent shall be refused as regards premises approval for those premises; or
- (b) where none of the premises for which premises approval has been granted are practice premises, the outline consent shall lapse.

(14) The Primary Care Trust shall notify its determination under paragraph (11) to the applicant and those persons to whom notice of the application under regulation 61 was required to be given under regulation 33(2) and (3).

(15) Where the Primary Care Trust has determined that—

- (a) the provisional date shall be extended under paragraph (8);
- (b) the application for outline consent shall be refused under paragraph (13)(a); or
- (c) outline consent shall lapse under paragraph (13)(b),

the applicant may appeal under regulation 38 to the Secretary of State against any such determination by giving notice of appeal in accordance with regulation 38(5).

(16) Premises approval shall take effect when the relating outline consent takes effect.

Lapse of outline consent and premises approval

63.—(1) An outline consent shall cease to have effect—

- (a) where no arrangement under regulation 60 has been made pursuant to it within 12 months from its taking effect;
- (b) where more than 12 months have elapsed since the last provision of drugs and appliances under an arrangement made pursuant to regulation 60;
- (c) in accordance with regulations 62(10) or (13); or

- (d) where there is a practice amalgamation and following the amalgamation there are no practice premises which have premises approval.
- (2) Premises approval shall cease to have effect in relation to—
- (a) listed premises which have permanently ceased to be practice premises;
 - (b) listed premises which have not been used for dispensing by any doctor authorised to dispense from those premises for six months or such longer period as the Primary Care Trust may for good cause allow;
 - (c) listed premises where a doctor who has outline consent to dispense from those premises has notified the Primary Care Trust that all the doctors who have authority to dispense from those premises have ceased to do so;
 - (d) listed premises where there is no doctor with premises approval in respect of them remaining on the dispensing doctor list; or
 - (e) listed premises which were granted premises approval under regulation 66(3), where no practice amalgamation takes place within the period specified in regulation 66(7).
- (3) Premises approval shall cease to have effect where the relating outline consent ceases to have effect.

Premises approval: change of premises before outline consent takes effect

64.—(1) Where—

- (a) outline consent has been granted but has not yet taken effect under regulation 62; and
- (b) before the provisional date the doctor who made the application under regulation 61 intends to change the premises from which he wishes to dispense,

he may apply to the Primary Care Trust in writing for the Primary Care Trust to determine whether premises approval should be given in relation to the new premises, and the Primary Care Trust shall make the determination in accordance with paragraph (2).

(2) If the Primary Care Trust is satisfied that the change of premises is a minor relocation it may grant premises approval for those premises, but if it is not so satisfied the application for the premises approval to be given in relation to the new premises shall be refused.

(3) The Primary Care Trust shall notify those persons to whom notice of the application under regulation 61 was required to be given and applicants in relation to the outstanding applications, of its determination under paragraph (2).

(4) The determination by the Primary Care Trust under paragraph (2) may be appealed to the Secretary of State under regulation 38 by the applicant.

Premises approval: additional and new premises after outline consent has taken effect

65.—(1) A doctor who—

- (a) has been granted outline consent which has taken effect; or
- (b) provides pharmaceutical services in reliance on regulation 60(3)(b),

and who wishes to be granted premises approval in relation to premises in addition to those in respect of which premises approval has been given (“additional premises”) may apply to all the appropriate Primary Care Trusts and—

- (i) the application shall be determined by the relevant Primary Care Trust, and
- (ii) regulations 18, 20(2), 34 to 36(1) and (3) to (9), 37, 38 and 61 and this regulation shall apply to such an application as they apply to an application for outline consent under regulation 61.

(2) For the purposes of this Regulation—

- (a) the “appropriate Primary Care Trusts” are those who hold dispensing doctor lists on which the doctor making the application is included; and

(b) the “relevant Primary Care Trust” is the Primary Care Trust in whose area the additional premises are situated.

(3) A doctor wishing to be granted premises approval in relation to premises (“new premises”) where he wishes to dispense instead of listed premises may apply to all the appropriate Primary Care Trusts and the application shall be determined by the relevant Primary Care Trust in accordance with paragraph (4).

(4) The relevant Primary Care Trust shall—

(a) grant the application made in accordance with paragraph (3) where—

(i) the new premises are less than 500 metres by the most practicable route on foot from the listed premises which they are to replace, or

(ii) the Primary Care Trust is otherwise satisfied that granting the application would not result in a significant change in the arrangements for the provision of pharmaceutical services or dispensing services in any part of a controlled locality,

provided that no further applications shall be granted under this sub-paragraph for a period of 12 months beginning with the date on which the doctor commenced providing services from the new premises unless the Primary Care Trust shall for good cause allow;
or

(b) in any other case determine the application in accordance with paragraph (1) as if the references to additional premises were to new premises.

(5) The Primary Care Trust shall notify its determination under paragraph (4)(a) to the persons to whom the notice is required to be given under regulation 33(2) and (3) and to the appropriate Primary Care Trusts.

(6) A determination by the Primary Care Trust may be appealed to the Secretary of State under regulation 38 by the applicant and any of the persons notified under paragraph (5) apart from any Local Pharmaceutical Committee or any Local Medical Committee.

(7) Subject to paragraph (8), when granted in relation to new or additional premises, the premises approval shall take effect from the date of notification of the grant and for this purpose the date of the notification of a grant of any application shall be—

(a) where no appeal is made under paragraph (6) against the decision of the Primary Care Trust, the date after the expiry of the period of 30 days beginning with the date on which notice of that decision is given under paragraph (5); or

(b) where such an appeal is made, the date on which the Secretary of State gives notice of his decision under regulation 38.

(8) Where—

(a) the premises approval is granted in relation to additional premises; and

(b) in relation to the premises for which the authority is granted there were, at the date of the grant, outstanding applications,

the premises approval shall provisionally take effect on the date which is the day after the end of a period of one year, or such longer period (not exceeding three months) as the Primary Care Trust may for good cause allow before the expiration of that year, from the final resolution of any outstanding application.

(9) The Primary Care Trust may grant temporary premises approval to a doctor who has outline consent and premises approval in relation to additional or new premises where it considers it desirable to do so to secure the adequate provision of pharmaceutical services in the area served by the premises, and renew any such temporary authority granted, to secure such adequate provision, and where it does so it shall—

(a) notify those persons to whom notice of the application under regulation 61 was required to be given under regulation 32(2) and (3) and applicants in relation to outstanding applications;

(b) state the period during which the temporary premises approval is to apply; and

(c) include those premises in the dispensing doctors list in relation to that doctor.

(10) Temporary premises approval may be granted for a period not exceeding 12 months, and may be renewed for a further period not exceeding three months.

Premises approval: practice amalgamations

66.—(1) For the purposes of these Regulations, “a practice amalgamation” occurs where either—

- (a) two or more providers of primary medical services merge; or
- (b) a GMS contractor, PMS contractor, an APMS contractor or a doctor who provides primary medical services for a PCTMS practice is employed or engaged by another GMS contractor, PMS contractor or APMS contractor or by a Primary Care Trust to provide services within another PCTMS practice,

as a result of which two or more patient lists are combined.

(2) If, following a practice amalgamation, all the practice premises of the new practice are premises in respect of which premises approval was in effect immediately prior to the practice amalgamation, then outline consent and premises approval shall continue to have effect.

(3) Where there is, or will be, a practice amalgamation and none or not all of the practice premises of the new practice are, or will be, premises in respect of which premises approval was in effect immediately prior to the practice amalgamation, a doctor who has been granted outline consent and premises approval which is in effect either immediately before the practice amalgamation or the date of the application under this paragraph, may make an application for premises approval, and it shall be determined as provided in regulation 65 as if it were an application from a doctor with premises approval to have the right to dispense from—

- (a) additional premises where the premises approval is required for additional premises as defined in regulation 65(1); or
- (b) new premises where the premises approval is required for new premises as defined in regulation 65(3),

and the Primary Care Trust may grant temporary premises approval under regulation 65(9).

(4) An application mentioned in paragraph (3) may be made before or after the practice amalgamation takes place, and where the practice amalgamation takes effect before the application has been finally determined—

- (a) any premises approval in effect at the date of the practice amalgamation shall have effect from the date of the amalgamation as if it were a temporary approval under regulation 65(9) for a period stated by the Primary Care Trust not exceeding one year; and
- (b) the new practice shall have temporary premises approval from the date of the practice amalgamation to dispense from any premises mentioned in the application for a period stated by the Primary Care Trust not exceeding one year.

(5) When the practice amalgamation takes effect the doctors shall notify all Primary Care Trusts in whose area the amalgamated practice is situated that the practice amalgamation has taken place.

(6) Subject to paragraph (7), where an application made under paragraph (3) was granted before the practice amalgamation takes place, premises approval shall take effect from the date of the practice amalgamation.

(7) Where an application was made under paragraph (3) before the practice amalgamation takes place and the practice amalgamation has not taken place before the end of a period of one year beginning with the date that premises approval was granted under that paragraph, that grant shall lapse.

(8) Where an application under paragraph (3) for premises approval is refused either for all or any of the premises specified in the application, whether before or after the practice amalgamation takes place, the doctors who had premises approval prior to making the application, and any other doctor in the new practice after that date shall have residual premises approval.

(9) For the purposes of this regulation “residual premises approval” means premises approval to dispense—

- (a) from premises in respect of which the doctor or another doctor in his practice had premises approval at the time of the application in relation to the practice amalgamation; and
- (b) to—
 - (i) a patient for whom the doctor making the application is authorised to provide pharmaceutical services on the date the application was refused, but excluding any such patient who ceases to be a patient mentioned in regulation 60(1)(b) or (c); or
 - (ii) a patient who is not mentioned in paragraph (i) but who is mentioned in regulation 60(1)(a) or (d) and for whom the doctor making the application is authorised to provide pharmaceutical services on the date the application was refused.

(10) For the purposes of paragraph (9), regulation 60(1)(b) or (c) shall be read as if the words “and one of the conditions specified in paragraph (3) is satisfied in his case” were omitted.

Premises approval – transitional provisions

67.—(1) This regulation applies to a doctor who has been finally granted outline consent under the 1992 Regulations, or for whom arrangements or requirements were in effect under the 1992 Regulations, to provide drugs or appliances to patients and that consent is, or those arrangements or requirements are, in effect on the date these regulations come into force.

(2) For the purposes of this regulation, “relevant premises” means—

- (a) premises from which, at the date of notification under paragraph (5), the doctor is providing primary medical services; or
- (b) premises in addition to or in place of the premises specified in paragraph (a) where, immediately before the date these Regulations came into force, the doctor intended to dispense.

(3) The Primary Care Trust shall determine whether or not to grant premises approval to relevant premises in accordance with paragraphs (4) to (6).

(4) Before the end of the period of 30 days beginning with the date that these Regulations come into force, the Primary Care Trust shall notify each doctor who is on its dispensing doctors list that—

- (a) the Primary Care Trust is required to make a determination under paragraph (3) as to whether or not to grant premises approval in respect of the relevant premises; and
- (b) he may make written representations to the Primary Care Trust in relation to such a determination within the period of 30 days beginning with the date of the Primary Care Trust’s notification or such longer period as the Primary Care Trust may for good cause allow.

(5) The Primary Care Trust shall—

- (a) also notify the Local Medical Committee and the Local Pharmaceutical Committee which were required to be sent a copy of the application under regulations 33(2) and (3) and inform them that they may make written representations within the period of 30 days beginning with the date of the Primary Care Trust’s notification;
- (b) consider any representations received from the Committees mentioned in sub-paragraph (a) and the doctor;
- (c) determine that the doctor has premises approval for premises which are, or are part of, relevant premises; and
- (d) notify its decision to the doctor, the Committees mentioned in sub-paragraph (a), any person providing pharmaceutical services or dispensing services in the Primary Care Trust’s area whose interests might, in the opinion of the Primary Care Trust, be affected and all Patients’ Forums in that area.

(6) The Primary Care Trust shall grant premises approval under paragraph (3) where—

- (a) it is satisfied that the relevant premises were, prior to the coming into force of these Regulations, being routinely used to provide dispensing services; or
- (b) outline consent had been granted under the 1992 Regulations after 31st March 2004 in respect of the relevant premises.

(7) The Primary Care Trust shall not refuse to grant premises approval under paragraph (3) by reason of the relevant premises being within 1.6 kilometres of any pharmacy.

(8) The Primary Care Trust's determination under paragraph (5)(c) may be appealed to the Secretary of State by a person notified of the determination under paragraph (5)(d) except the Committees mentioned in paragraph (5)(a), and regulations 38(5) to (15) shall apply to such appeals except that, for this purpose, regulation 38 shall be read as if—

- (a) in paragraph (7) the reference to “those persons mentioned in paragraph (3)(a)” were a reference to those persons notified under paragraph (5)(d);
- (b) in paragraph (12) the list of persons to whom notice of the hearing should be sent were a reference to the persons notified under paragraph (5)(d); and
- (c) in paragraph (14) sub-paragraphs (b), (c) and (d) were omitted.

(9) Until—

- (a) the date of the determination of the Primary Care Trust under paragraph (3); or
- (b) the date that any appeal under paragraph (7) is decided,

whichever is the later, a doctor shall be deemed to have been granted premises approval for the relevant premises, but he may not make any application under regulation 64 or 65 by virtue of this paragraph.

Dispensing doctor lists

68.—(1) A Primary Care Trust shall prepare, maintain and publish a list, to be called the dispensing doctor list, of the names of those doctors authorised or required by the Primary Care Trust under regulation 60 to provide pharmaceutical services to their patients and who are actually doing so.

(2) The dispensing doctor list shall indicate the name and address of the relevant GMS contractor, PMS contractor or APMS contractor from whose premises any doctor whose name is included in that list performs primary medical services.

(3) Where the doctor whose name is included in the dispensing doctor list provides primary medical services within a PCTMS practice, the list shall give the name and address of the Primary Care Trust.

(4) The dispensing doctor list shall, in addition to the information required under paragraphs (2) and (3)—

- (a) include the premises in relation to which the doctor has premises approval;
- (b) state in relation to each premises included—
 - (i) if premises approval is deemed, temporary or residual, that this is the case,
 - (ii) the date on which premises approval took effect or where it has not taken effect the date that it was finally granted,
- (c) state the area in relation to which there is outline consent and premises approval; and
- (d) include and identify separately, any premises in relation to which the doctor has outstanding applications for premises approval.

Removal of entries from dispensing doctor lists

69. A Primary Care Trust shall remove the name of a doctor from its dispensing doctor list where the Primary Care Trust determines that—

- (a) the doctor has died;

- (b) the doctor is no longer performing primary medical services within the area of the Primary Care Trust;
- (c) more than 12 months have elapsed since the doctor last provided drugs or appliances under an arrangement made pursuant to regulation 60 with the Primary Care Trust; or
- (d) the doctor has been removed from the medical performers list.

PART 6

Miscellaneous

Publication of particulars

70.—(1) A Primary Care Trust shall make available for inspection at its offices copies of—

- (a) its pharmaceutical lists;
- (b) the terms of service for pharmacists;
- (c) the terms of service for doctors who provide pharmaceutical services;
- (d) the terms of service for suppliers of appliances;
- (e) the Drug Tariff;
- (f) determinations made by the Primary Care Trust by virtue of regulation 56(2);
- (g) its dispensing doctor list; and
- (h) its ETP list,

and shall keep them up to date.

(2) The Primary Care Trust may—

- (a) make such documents available for inspection at such other places in its locality as appear to it convenient for informing all persons interested; or
- (b) publish at such places a notice of the places and times at which copies of such documents may be seen.

(3) The Primary Care Trust shall send a copy of its pharmaceutical list and of its dispensing doctor list to the Local Medical Committee, the Local Dental Committee and the Local Pharmaceutical Committee, and shall, within 14 days of any alteration in either of those lists, so inform them in writing.

List of chemists providing an ETP service

71.—(1) A Primary Care Trust shall prepare, maintain and publish a list (to be called the ETP list) of all chemists in its area who participate in the ETP service.

(2) The list referred to in paragraph (1) shall include—

- (a) the name of the chemist; and
- (b) the address of the premises at which the ETP service is provided.

Exercise of choice of chemist in certain cases

72. An application to a chemist for pharmaceutical services may be made (other than by the chemist concerned)—

- (a) on behalf of any child by either parent, or in the absence of both parents, the guardian or other person who has the care of the child;
- (b) on behalf of any person under 18 years of age who is—

- (i) in the care of an authority to whose care he has been committed under the provisions of the Children Act 1989(a), by a person duly authorised by that authority, or
- (ii) in the care of a voluntary organisation, by that organisation or a person duly authorised by them;
- (c) on behalf of any adult who is incapable of making such an application or authorising such an application to be made on their behalf, by a relative or the primary carer of that person; or
- (d) on behalf of any other person by any duly authorised person.

Transitional provisions

73.—(1) Any application under the 1992 Regulations for inclusion in the pharmaceutical list or outline consent that has been received by a Primary Care Trust on or before 31st March 2005 shall be determined in accordance with the provisions of the 1992 Regulations until that application is finally determined.

(2) Any appeal under the 1992 Regulations that is—

- (a) received by the Secretary of State on or before 31st March 2005; or
- (b) made after the coming into force of these Regulations in respect of an application determined in accordance with paragraph (1),

shall be determined in accordance with the provisions of the 1992 Regulations.

(3) Any application granted under the 1992 Regulations (whether or not pursuant to paragraph (1) or (2)) shall be treated as granted under these Regulations for the purposes of regulation 39 unless notice was given under regulation 4(9) of the 1992 Regulations before the coming into force of these Regulations in which case regulation 4(9) and (11) of the 1992 Regulations shall continue to apply.

(4) Where by virtue of paragraph (3) regulation 39 applies, regulation 39 shall be read as if any reference to—

- (a) regulation 5(1)(a) were a reference to regulation 4(2)(a) of the 1992 Regulations;
- (b) regulation 5(1)(b) were a reference to regulation 4(2)(b) of the 1992 Regulations;
- (c) regulation 22(3) were a reference to regulation 12 of the 1992 Regulations;
- (d) regulation 27(1) were a reference to regulation 11(1) of the 1992 Regulations;
- (e) regulations 33 to 36 were a reference to regulation 12 of the 1992 Regulations;
- (f) regulation 37(1) were a reference to regulation 12(11) of the 1992 Regulations; and
- (g) regulation 38 were a reference to regulation 13 of the 1992 Regulations.

(5) Where preliminary consent was granted under regulation 14 of the 1992 Regulations (whether or not pursuant to paragraph (1) or (2)) and no application has been made under regulation 15 of the 1992 Regulations on the date of the coming into force of these Regulations, regulation 41 shall apply as if the preliminary consent had been granted under regulation 40.

(6) Where, pursuant to paragraph (1), an application for outline consent falls to be determined under the 1992 Regulations, the Primary Care Trust shall determine at the same time whether or not to grant premises approval in respect of relevant premises within the meaning of regulation 67(2), and any appeal relating to the Primary Care Trust's determination under this paragraph shall be dealt with as if it were a refusal of outline consent.

Transitional arrangements in respect of terms of service

74.—(1) A pharmacist who is providing pharmaceutical services on 31st March 2005 by virtue of a particular entry on a pharmaceutical list (or who is included in a pharmaceutical list subsequent to that date by virtue of regulation 73), when providing pharmaceutical services

(a) 1989 c.41.

pursuant to that entry, need not comply with the terms of service set out in Schedule 1, apart from—

- (a) paragraph 11(1), Part 3 and paragraphs 29 to 31 of that Schedule, until 1st October 2005, provided that until that date he complies with the terms of service set out in Parts I and II of Schedule 2 to the 1992 Regulations, apart from paragraph 4 of that Schedule; and
- (b) if he provides an ETP service, the requirements of that Schedule in respect of electronic prescriptions and otherwise in connection with the ETP service.

(2) A supplier of appliances who is providing pharmaceutical services on 31st March 2005 by virtue of a particular entry on a pharmaceutical list (or who is included in a pharmaceutical list subsequent to that date by virtue of regulation 73), when providing pharmaceutical services pursuant to that entry, need not comply with the terms of service set out in Schedule 3, apart from—

- (a) paragraphs 9(1), 10 to 13 and 16 to 18 of that Schedule, until 1st October 2005, provided that until that date he complies with the terms of service set out in Parts I and II of Schedule 2 to the 1992 Regulations, apart from paragraph 4 of that Schedule; and
- (b) if he provides an ETP service, the requirements of that Schedule in respect of electronic prescriptions and otherwise in connection with an ETP service.

(3) Where, before this article comes into force or by virtue of this article, a complaint is being investigated under a complaints procedure mentioned in paragraph 10A or 10B of Schedule 2 to the 1992 Regulations, a pharmacist or supplier of appliances shall—

- (a) in the case of a complaint being investigated under a complaints procedure mentioned in the said paragraph 10A, dispose of the matter in accordance with that paragraph; and
- (b) in the case of a complaint being investigated under a complaints procedure mentioned in the said paragraph 10B, co-operate with the investigation in the manner set out in that paragraph.

(4) Where, before this article comes into force, a chemist is the subject of proceedings under paragraph 4 of Schedule 2 to the 1992 Regulations in respect of issuing of a direction as to the days on which or hours at which he is to provide pharmaceutical services—

- (a) those proceedings shall be disposed of in accordance with paragraph 4 of Schedule 2 to the 1992 Regulations; and
- (b) any direction issued as a result of those proceedings is a direction issued under paragraph 4 of Schedule 2 to the 1992 Regulations for the purposes of these Regulations.

(5) A dispensing doctor who is providing pharmaceutical services on 31st March 2005 by virtue of a particular entry on a dispensing doctor list (or who is included in a dispensing doctor list subsequent to that date by virtue of regulation 73), when he provides pharmaceutical services pursuant to that entry, need not comply with the terms of service set out in Schedule 2 until 1st October 2005, provided that—

- (a) until that date he complies with the terms of service set out in Parts I and III of Schedule 2 to the 1992 Regulations; and
- (b) if he provides an ETP service, he complies with the requirements of Schedule 2 in respect of electronic prescriptions and otherwise in connection with an ETP service.

Minor and consequential amendments and revocations

75.—(1) The enactments listed in Schedule 5 are amended as there specified.

(2) The enactments listed in Schedule 6 are revoked to the extent there specified.

10th March 2005

Rosie Winterton
Minister of State
Department of Health

TERMS OF SERVICE OF PHARMACISTS

PART 1

GENERAL

Incorporation of provisions

1. Any provisions of the following affecting the rights and obligations of pharmacists shall be deemed to form part of the terms of service for pharmacists—

- (a) the Regulations;
- (b) the Drug Tariff in so far as it lists drugs and appliances for the purposes of section 41 of the Act;
- (c) so much of Part II of the National Health Service (Service Committees and Tribunal) Regulations 1992^(a) as relates to—
 - (i) the investigation of questions arising between pharmacists and persons receiving pharmaceutical services and other investigations to be made by the pharmaceutical discipline committee and the joint discipline committee and the action which may be taken by the Primary Care Trust as a result of such investigations, and
 - (ii) appeals to the Secretary of State from decisions of the Primary Care Trust; and
- (d) so much of regulation 3 of the Patients' Forums (Functions) Regulations 2003^(b) as relate to the entry and inspection of premises either owned or controlled by the pharmacist or where pharmaceutical services are provided by him.

Division of responsibilities between individuals and corporate bodies

2.—(1) To the extent that this Schedule imposes a requirement on a pharmacist in respect of an activity which could only, or would normally, be undertaken by a natural person—

- (a) if the pharmacist is a registered pharmacist—
 - (i) that registered pharmacist must comply with that requirement, or
 - (ii) if he employs or engages a registered pharmacist in connection with the provision of pharmaceutical services, that registered pharmacist must either comply with that requirement or secure compliance with that requirement by a registered pharmacist whom he employs or engages; and
- (b) if the pharmacist is not a natural person, that pharmacist must secure compliance with that requirement by the registered pharmacists whom he employs or engages,

and references in this Schedule to a pharmacist shall be construed accordingly.

(2) Where this Schedule imposes a requirement on the director or superintendent of a body corporate that is on a pharmaceutical list, breach of that requirement shall be deemed to be a breach by the body corporate of its terms of service.

(a) S.I. 1992/664.

(b) S.I. 2003/2124. Regulation 3 has been amended by S.I. 2004/540, 696 and 865.

PART 2

ESSENTIAL SERVICES

Essential services

3. For the purposes of these Regulations, “essential services” means—
- (a) the services described in this Part; and
 - (b) the activities described in this Part to be carried out in connection with those services.

Dispensing services

4. A pharmacist shall, to the extent that paragraphs 5 to 9 require and in the manner described in those paragraphs, provide proper and sufficient drugs and appliances to persons presenting prescriptions for drugs or appliances by health care professionals in pursuance of their functions in the health service, the Scottish health service or the Northern Ireland health service.

Dispensing of drugs and appliances

5.—(1) In this Part, “signed” includes signature with a prescriber’s advanced electronic signature.

- (2) Subject to the following provisions of this Part, where—
- (a) any person presents a non-electronic prescription form which contains—
 - (i) an order for drugs, not being Scheduled drugs, or for appliances, not being restricted availability appliances, signed by a prescriber,
 - (ii) an order for a drug specified in Schedule 2 to the Prescription of Drugs Regulations, signed by a prescriber and including the reference “SLS”, or
 - (iii) an order for a restricted availability appliance, signed by a prescriber and including the reference “SLS”; or
 - (b) subject to sub-paragraph (4), the pharmacist receives from the ETP service an electronic prescription form which contains an order of a kind specified in paragraph (a)(i) to (iii) and—
 - (i) any person requests the provision of drugs or appliances in accordance with that prescription, or
 - (ii) the pharmacist has previously arranged with the patient that he will dispense that prescription on receipt,

a pharmacist shall, with reasonable promptness, provide the drugs so ordered, and such of the appliances so ordered as he supplies in the normal course of his business.

- (3) Subject to the following provisions of this Part, where—
- (a) any person presents a non-electronic repeatable prescription which contains—
 - (i) an order for drugs, not being Scheduled drugs or controlled drugs within the meaning of the Misuse of Drugs Act 1971(a), other than a drug which is for the time being specified in Schedule 4 or 5 to the Misuse of Drugs Regulations 2001(b), signed by a repeatable prescriber,
 - (ii) an order for a drug specified in Schedule 2 to the Prescription of Drugs Regulations, not being 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 4 or 5 to the Misuse of Drugs Regulations 2001, signed by a repeatable prescriber and including the reference “SLS”,

(a) 1971 c.38: see section 2(1)(a) of that Act, which defines “controlled drug” for the purposes of that Act.
(b) S.I. 2001/3998. Schedule 4 has been amended by S.I. 2003/1432.

- (iii) an order for appliances, not being restricted availability appliances, signed by a repeatable prescriber, or
 - (iv) an order for a restricted availability appliance, signed by a repeatable prescriber, and including the reference “SLS”,
- and also presents an associated batch issue; or
- (b) the pharmacist receives from the ETP service an electronic repeatable prescription which contains an order of a kind specified in paragraph (a)(i) to (iv) and—
 - (i) any person requests the provision of drugs or appliances in accordance with that repeatable prescription, or
 - (ii) the pharmacist has previously arranged with the patient that he will dispense that repeatable prescription on receipt,

a pharmacist shall, with reasonable promptness, provide the drugs so ordered, and such of the appliances so ordered as he supplies in the normal course of his business.

(4) A pharmacist shall not provide under an electronic prescription form 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 4 or 5 to the Misuse of Drugs Regulations 2001.

(5) For the purposes of this paragraph, a non-electronic repeatable prescription for drugs or appliances shall be taken to be presented even if the person who wishes to obtain the drugs or appliances does not present that prescription, where—

- (a) the pharmacist has that prescription in his possession; and
- (b) that person presents, or the pharmacist has in his possession, an associated batch issue.

Urgent supply without a prescription

6. Where, in a case of urgency, a prescriber personally known to a pharmacist requests him to provide a drug, the pharmacist may provide that drug before receiving a prescription form or repeatable prescription, provided that—

- (a) that drug is not a Scheduled drug;
- (b) that drug is not 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 4 or 5 to the Misuse of Drugs Regulations 2001; and
- (c) the prescriber undertakes to—
 - (i) give the pharmacist a non-electronic prescription form or non-electronic repeatable prescription in respect of the drug within 72 hours, or
 - (ii) transmit to the ETP service within 72 hours an electronic prescription.

Preliminary matters before providing ordered drugs or appliances

7.—(1) If a person specified in paragraph (2) asks the pharmacist to do so—

- (a) the pharmacist shall give an estimate of the time when the drugs or appliances will be ready; and
- (b) if they are not ready by then, the pharmacist shall give a revised estimate of the time when they will be ready (and so on).

(2) The persons referred to in paragraph (1) are a person—

- (a) presenting a non-electronic prescription form or non-electronic repeatable prescription; or
- (b) requesting the provision of drugs or appliances in accordance with an electronic prescription form or a repeatable prescription.

(3) Before providing any drugs or appliances in accordance with a prescription form or a repeatable prescription the pharmacist shall ask any person who makes a declaration that the

person named on the prescription form or the repeatable prescription does not have to pay the charges specified in regulation 3(1) or (1A) of the Charges Regulations by virtue of either—

- (a) entitlement to exemption under regulation 7(1) of the Charges Regulations; or
- (b) entitlement to remission of charges under regulation 5 of the Remission of Charges Regulations,

to produce satisfactory evidence of such entitlement, unless the declaration is in respect of entitlement to exemption by virtue of sub-paragraph (a), (c), (d), (e), (f) or (g) of regulation 7(1) of the Charges Regulations or in respect of entitlement to remission by virtue of regulation 5(1)(e) or (2) of the Remission of Charges Regulations, and at the time of the declaration the pharmacist already has such evidence available to him.

(4) If, in the case of a non-electronic prescription form or non-electronic repeatable prescription, no satisfactory evidence, as required by sub-paragraph (3), is produced to the pharmacist, the pharmacist shall endorse the form on which the declaration is made to that effect.

(5) In the case of an electronic prescription, the pharmacist shall transmit to the ETP service—

- (a) in a case where exemption from or remission of charges is claimed for all or some of the items included in the prescription, a record of—
 - (i) the exemption category specified in regulation 7(1) of the Charges Regulations or the ground for remission under regulation 5 of the Remission of Charges Regulations which it is claimed applies to the case, and
 - (ii) whether or not satisfactory evidence was produced to him as required by sub-paragraph (3);
- (b) in any case where a charge is due, confirmation that the relevant charge was paid; and
- (c) in a case of a prescription for or including contraceptive substances, confirmation that no charge was payable in respect of those substances.

Providing ordered drugs or appliances

8.—(1) Where a pharmacist is presented with, or receives from the ETP service, a prescription form or a repeatable prescription, the pharmacist shall only provide the drugs or appliances so ordered—

- (a) if the prescription form or repeatable prescription is duly signed and completed as described in paragraph 5(2) or (3); and
- (b) in accordance with the order on the prescription form or repeatable prescription,

subject to any regulations in force under the Weights and Measures Act 1985^(a) and the following provisions of this Part.

(2) Drugs or appliances so ordered shall be provided either by or under the direct supervision of a pharmacist.

(3) Where the pharmacist referred to in sub-paragraph (2) is employed by a pharmacist, the pharmacist must not be someone—

- (a) who—
 - (i) has been disqualified under section 46(2)(b) of the Act (or under any corresponding provision in force in Scotland or Northern Ireland) from inclusion in the pharmaceutical list of a Primary Care Trust (or, in Scotland, of a Health Board or, in Northern Ireland, of a Health and Social Services Board), and
 - (ii) is the subject of a declaration under section 46(2)(c) of the Act (or any corresponding provision in force in Scotland or Northern Ireland) that he is not fit to be engaged in any capacity in the provision of pharmaceutical services; or
- (b) who is suspended.

(a) 1985 c.72.

(4) If the order is for an appliance of a type requiring measuring and fitting by the pharmacist (for example a truss), the pharmacist shall make all necessary arrangements for—

- (a) measuring the person named on the prescription form or repeatable prescription for the appliance; and
- (b) fitting the appliance.

(5) If the order is for a drug or appliance included in the Drug Tariff, the British National Formulary (including any Appendix published as part of that Formulary), the Dental Practitioner's Formulary, the European Pharmacopoeia or the British Pharmaceutical Codex, the drug or appliance provided shall comply with the standard or formula specified therein.

(6) If the order—

- (a) is an order for a drug; but
- (b) is not an order for 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 4 or 5 to the Misuse of Drugs Regulations 2001,

and does not prescribe its quantity, strength or dosage, a pharmacist may provide the drug in such strength and dosage as in the exercise of his professional skill, knowledge and care he considers to be appropriate and, subject to sub-paragraph (7), in such quantity as he considers to be appropriate for a course of treatment for a period not exceeding five days.

(7) Where an order to which sub-paragraph (6) applies is for—

- (a) an oral contraceptive substance;
- (b) a drug, which is available for supply as part of pharmaceutical services only together with one or more other drugs; or
- (c) an antibiotic in a liquid form for oral administration in respect of which pharmaceutical considerations require its provision in an unopened package,

which is not available for provision as part of pharmaceutical services except in such packages that the minimum size available contains a quantity appropriate to a course of treatment for a period of more than 5 days, the pharmacist may provide the minimum size available package.

(8) Where any drug to which this paragraph applies (that is, a drug that is not one to which the Misuse of Drugs Act 1971 applies, unless it is a drug for the time being specified in Schedule 5 to the Misuse of Drugs Regulations 2001), ordered by a prescriber on a prescription form or repeatable prescription, is available for provision by a pharmacist in a pack in a quantity which is different to the quantity which has been so ordered, and that drug is—

- (a) sterile;
- (b) effervescent or hygroscopic;
- (c) a liquid preparation for addition to bath water;
- (d) a coal tar preparation;
- (e) a viscous preparation; or
- (f) packed at the time of its manufacture in a calendar pack or special container,

the pharmacist shall, subject to sub-paragraph (9), provide the drug in the pack whose quantity is nearest to the quantity which has been so ordered.

(9) A pharmacist shall not provide, pursuant to sub-paragraph (8), a drug in a calendar pack where, in his opinion, it was the intention of the prescriber who ordered the drug that it should be provided only in the exact quantity ordered.

(10) In this paragraph—

- (a) “calendar pack” means a blister or strip pack showing the days of the week or month against each of the several units in the pack; and
- (b) “special container” means any container with an integral means of application or from which it is not practicable to dispense an exact quantity.

(11) Except as provided in sub-paragraph (12), a pharmacist shall not provide a Scheduled drug in response to an order by name, formula or other description on a prescription form or repeatable prescription.

(12) Where a drug has an appropriate non-proprietary name and it is ordered on a prescription form or repeatable prescription either by that name or by its formula, a pharmacist may provide a drug which has the same specification notwithstanding that it is a Scheduled drug, provided that where a Scheduled drug is in a pack which consists of a drug in more than one strength, such provision does not involve the supply of part only of the pack.

(13) Where a drug which is ordered as specified in sub-paragraph (12) combines more than one drug, that sub-paragraph shall apply only if the combination has an appropriate non-proprietary name, whether the individual drugs which it combines do so or not.

(14) A pharmacist shall provide any drug which he is required to provide under paragraph 5 in a suitable container.

Refusal to provide drugs or appliances ordered

9.—(1) A pharmacist may refuse to provide the drugs or appliances ordered on a prescription form or repeatable prescription where—

- (a) the pharmacist reasonably believes that it is not a genuine order for the person named on the prescription form or the repeatable prescription (for example because he reasonably believes it has been stolen or forged);
- (b) it appears to the pharmacist that there is an error on the prescription form or on the repeatable prescription or, in the case of a non-electronic repeatable prescription, its associated batch issue (including a clinical error made by the prescriber) or that, in the circumstances, providing the drugs or appliances would be contrary to the pharmacist's clinical judgement;
- (c) the pharmacist or other persons on the premises are subjected to or threatened with violence by the person presenting the prescription form or repeatable prescription or requesting the provision of drugs or appliances in accordance with an electronic prescription form or a repeatable prescription, or by any person accompanying that person; or
- (d) the person presenting the prescription form or repeatable prescription or requesting the provision of drugs or appliances in accordance with an electronic prescription form or a repeatable prescription, or any other person accompanying that person, commits or threatens to commit a criminal offence.

(2) A pharmacist shall refuse to provide a drug ordered on a prescription form or repeatable prescription where the order is for a prescription only medicine which the prescriber was not entitled to prescribe.

(3) A pharmacist shall refuse to provide drugs or appliances ordered on a repeatable prescription where—

- (a) he has no record of that prescription;
- (b) he does not, in the case of a non-electronic repeatable prescription, have any associated batch issue and it is not presented to him;
- (c) it is not signed by a repeatable prescriber;
- (d) to do so would not be in accordance with any intervals specified in the prescription;
- (e) it would be the first time a drug or appliance had been provided pursuant to the prescription and the prescription was signed (whether electronically or otherwise) more than six months previously;
- (f) the repeatable prescription was signed (whether electronically or otherwise) more than one year previously;
- (g) the expiry date on the repeatable prescription has passed; or

- (h) where he has been informed by the repeatable prescriber that the prescription is no longer required.

(4) Where a patient requests the supply of drugs or appliances ordered on a repeatable prescription (other than on the first occasion that he makes such a request), a pharmacist shall only provide the drugs or appliances ordered if he is satisfied—

- (a) that the patient to whom the prescription relates—
 - (i) is taking or using, and is likely to continue to take or use, the drug or appliance appropriately, and
 - (ii) is not suffering from any side effects of the treatment which indicates the need or desirability of reviewing the patient's treatment;
- (b) that the medication regimen of the patient to whom the prescription relates has not altered in a way which indicates the need or desirability of reviewing the patient's treatment; and
- (c) there have been no changes to the health of the patient to whom the prescription relates which indicate the need or desirability of reviewing the patient's treatment.

Further activities to be carried out in connection with the provision of dispensing services

10. In connection with the services provided under paragraph 4, a pharmacist shall—

- (a) ensure that appropriate advice is given to patients about any drugs or appliances provided to them—
 - (i) to enable them to utilise the drugs or appliances appropriately, and
 - (ii) to meet the patient's reasonable needs for general information about the drugs or appliances;
- (b) provide appropriate advice to patients to whom they provide drugs or appliances on—
 - (i) the safe keeping of the drugs or appliances, and
 - (ii) returning unwanted drugs or appliances to the pharmacy for safe destruction;
- (c) provide appropriate advice to patients to whom they provide drugs or appliances in accordance with a repeatable prescription in particular on the importance of only requesting those items which they actually need;
- (d) provide a patient with a written note of any drug or appliance which is owed, and inform the patient when it is expected that the drug or appliance will become available;
- (e) keep and maintain records—
 - (i) of drugs and appliances provided, in order to facilitate the continued care of the patient;
 - (ii) in appropriate cases, of advice given and any interventions or referrals made (including clinically significant interventions in cases involving repeatable prescriptions), and
 - (iii) of notes provided under sub-paragraph (d);
- (f) undertake appropriate training in respect of repeat dispensing, having regard to any recommendations in respect of such training set out in the Drug Tariff;
- (g) if he takes possession of a non-electronic repeatable prescription or an associated batch issue, securely store that repeatable prescription or associated batch issue;
- (h) if he provides a drug or appliance under an electronic prescription, provide the patient, if he so requests, with a written record of the drugs or appliances ordered on that prescription and, in the case of an electronic repeatable prescription, of the number of occasions on which it can be dispensed;
- (i) maintain records of repeatable prescriptions in such a form as to provide a clear audit trail of supplies under the repeatable prescription (including dates and quantities supplied);
- (j) destroy any surplus batch issues relating to drugs or appliances—

- (i) which are not required, or
- (ii) where a patient is refused the drugs or appliances in pursuant to paragraph 9;
- (k) ensure that where a person is refused drugs or appliances pursuant to paragraphs 9(1)(b), (2), (3) or (4), the patient is referred back to the prescriber for further advice;
- (l) where a patient is provided with drugs or appliances under a repeatable prescription, notify the prescriber of any clinically significant issues arising in connection with the prescription and keep a record of that notification; and
- (m) notify the prescriber of any refusal to provide drugs or appliances pursuant to paragraph 9(4).

Additional requirements in relation to electronic prescribing

- 11.—(1) A pharmacist shall, if requested to do so by any person—
- (a) explain to him the ETP service, whether or not it is a service which is available through his pharmacy; and
 - (b) where the ETP service is not available through his pharmacy, provide him with contact details of at least two pharmacies in his area through which the service is available, if these details are known to the pharmacist.
- (2) Where the ETP service is available through his pharmacy, the pharmacist shall, if requested to do so by any person, enter in that person’s NHS Care Record—
- (a) where the person does not have a nominated dispensing contractor, the dispensing contractor chosen by that person; and
 - (b) where the person does have a nominated dispensing contractor—
 - (i) a replacement dispensing contractor, or
 - (ii) a further dispensing contractor, chosen by that person.
- (3) Paragraph (2)(b)(ii) shall not apply if the number of nominated dispensing contractors for that person would thereby exceed the maximum number permitted by the ETP service.
- (4) Regulation 72(a) to (c) shall apply to a request under this paragraph as it applies to an application to a chemist for pharmaceutical services.

Disposal service in respect of unwanted drugs

12. A pharmacist shall, to the extent paragraph 13 requires and in the manner described in that paragraph, accept and dispose of unwanted drugs presented to him for disposal.

Basic procedure in respect of unwanted drugs

13.—(1) Subject to paragraph (2), where a person presents to a pharmacist or any of his staff any drugs provided for a patient in, and which have been kept in—

- (a) a private household; or
- (b) a residential care home,

the pharmacist shall accept the drugs and dispose of them in accordance with sub-paragraph (3).

(2) A pharmacist shall not be required to accept any drugs for disposal unless the Primary Care Trust in whose list he is included has made arrangements for the collection and disposal of drugs of that description.

(3) On receipt of the drugs, the pharmacist shall—

- (a) where required to do so by the Primary Care Trust or by a waste disposal contractor retained by the Primary Care Trust, separate solid drugs or ampoules, liquids and aerosols from each other;

- (b) store the drugs in containers provided by the Primary Care Trust, or by a waste disposal contractor retained by the Primary Care Trust, for the purpose of storing drugs of that description; and
- (c) comply with any other statutory requirements in respect of storing or the disposal of drugs of that description (meeting those requirements are therefore an essential service for the purposes of these Regulations),

and shall co-operate with any suitable arrangements that the Primary Care Trust has in place for regular collection of the drugs from his premises by or on behalf of the Primary Care Trust.

Further activities to be carried out in connection with the disposal of unwanted drugs

14. In connection with the services provided under paragraph 12, a pharmacist shall—
- (a) ensure that he and any staff he has, are aware of the risks associated with the handling of waste drugs and the correct procedures to be used to minimise those risks; and
 - (b) ensure that he and any staff he has, have readily available and close to any place where waste drugs are stored appropriate protective equipment, including gloves, overalls and materials to deal with spillages.

Promotion of healthy lifestyles

15. A pharmacist shall, to the extent paragraphs 16 and 17 require, and in the manner set out in those paragraphs, promote public health messages to members of the public.

Prescription linked intervention

- 16.—(1) Where a person using a pharmacy—
- (a) presents a non-electronic prescription form or non-electronic repeatable prescription to a pharmacist or requests the provision of drugs or appliances in accordance with an electronic prescription; and
 - (b) it appears to the pharmacist that the person—
 - (i) has diabetes,
 - (ii) is at risk of coronary heart disease, especially those with high blood pressure, or
 - (iii) smokes or is overweight,

the pharmacist shall, as appropriate, provide advice to that person with the aim of increasing that person's knowledge and understanding of the health issues which are relevant to that person's personal circumstances.

(2) Advice given under sub-paragraph (1) may be backed up, as appropriate—

- (a) by the provision of written material (for example leaflets); and
- (b) by referring the person to other sources of information or advice.

(3) A pharmacist shall, in appropriate cases, keep and maintain a record of advice given pursuant to this paragraph, and that record shall be in a form that facilitates—

- (a) auditing of the provision of pharmaceutical services by the pharmacist; and
- (b) follow-up care for the person who has been given the advice.

Public health campaigns

17. A pharmacist shall, at the request of its Primary Care Trust, ensure that—
- (a) he and any staff he has, participate, in the manner reasonably requested by his Primary Care Trust, in up to six campaigns in each calendar year to promote public health messages to users of his pharmacy;

- (b) where requested to do so by the Primary Care Trust, he records the number of people to whom he or his staff have provided information as part of one of those campaigns.

Signposting

18. A pharmacist shall, to the extent paragraph 19 requires and in the manner set out in that paragraph, provide information to users of its pharmacy about other health and social care providers and support organisations.

Service outline in respect of signposting

19.—(1) Where it appears to a pharmacist or his staff, having regard to the need to minimise inappropriate use of health and social care services and of support services, that a person using his pharmacy—

- (a) requires advice, treatment or support that the pharmacist cannot provide; but
- (b) another provider, of which the pharmacist is aware, of health or social care services or of support services is likely to be able to provide that advice, treatment or support,

the pharmacist shall provide contact details of that provider to that person and shall, in appropriate cases, refer that person to that provider.

(2) Where appropriate, a referral under paragraph (1) may be made by means of a written referral note.

(3) The pharmacist shall, in appropriate cases, keep and maintain a record of any information given or referral made under paragraph (1) and that record shall be in a form that facilitates—

- (a) auditing of the provision of pharmaceutical services by the pharmacist; and
- (b) follow-up care for the person who has been given the information or in respect of whom the referral has been made.

Support for self-care

20. A pharmacist shall, to the extent paragraph 21 requires and in the manner set out in that paragraph, provide advice and support to people caring for themselves or their families.

Service outline in respect of support for self-care

21.—(1) Where it appears to a pharmacist or his staff, having regard to the need to minimise the inappropriate use of health and social care services, that a person using his pharmacy would benefit from advice from the pharmacist to help him manage a medical condition (including, in the case of a carer, to help the carer in assisting in the management of another person's medical condition), the pharmacist shall provide advice to the person using the pharmacy as regards managing the medical condition, including, as appropriate, advice—

- (a) on treatment options, including advice on the selection and use of appropriate drugs which are not prescription only medicines; and
- (b) on changes to the patient's lifestyle.

(2) The pharmacist shall, in appropriate cases, keep and maintain a record of any advice given under paragraph (1), and of any drugs supplied when the advice was given, and that record shall be in a form that facilitates—

- (a) auditing of the provision of pharmaceutical services by the pharmacist; and
- (b) follow-up care for the person to whom or in respect of whom the advice has been given.

PART 3

HOURS OF OPENING

Pharmacy opening hours: general

22.—(1) A pharmacist shall ensure that pharmaceutical services are provided at each of the premises from which he has undertaken to provide pharmaceutical services—

- (a) for not less than 40 hours each week;
- (b) for not less than 100 hours each week, in the case of premises in respect of which the condition imposed by regulation 13(2)(a) applies as regards the pharmacist's inclusion in a pharmaceutical list;
- (c) if his Primary Care Trust, or on appeal the Secretary of State, has directed (either under this Part or paragraph 4 of Schedule 2 to the 1992 Regulations) that he may provide pharmaceutical services at the premises for fewer than 40 hours per week, provided that he provides those services at set times and on set days, at the times and on the days so set;
- (d) if his Primary Care Trust, or on appeal the Secretary of State, has directed under paragraph 4 of Schedule 2 to the 1992 Regulations that he must provide pharmaceutical services at the premises for more than 40 hours per week, and at set times and on set days, at the times and on the days so set; or
- (e) if his Primary Care Trust, or on appeal the Secretary of State, has directed under this Part that he must provide pharmaceutical services at the premises for more than 40 hours each week—
 - (i) for the total number of hours each week required by virtue of that direction, and
 - (ii) as regards the additional hours for which he is required to provide pharmaceutical services by virtue of that direction, at the days on which and times at which he is required to provide pharmaceutical services during those additional hours, as set out in that direction,

but a Primary Care Trust may, in appropriate circumstances, agree a temporary suspension of services for a set period, where it has received three months notice of the proposed suspension.

(2) Subject to sub-paragraph (3), at each of the premises from which a pharmacist has undertaken to provide pharmaceutical services, he shall exhibit—

- (a) a notice specifying the days on which and times at which the premises are open for the provision of drugs and appliances;
- (b) at times when the premises are not open, a notice based on information provided by the Primary Care Trust, where practicable legible from outside the premises, specifying the addresses of other pharmacists included in the pharmaceutical list and the days on which and times at which drugs and appliances may be obtained from those addresses; and
- (c) at times when the premises are not open, a notice based on information provided by the Primary Care Trust, where practicable legible from outside the premises, specifying the addresses of LPS chemists in the neighbourhood, the type of local pharmaceutical services which those LPS chemists provide, and the days on which and times at which their premises are open.

(3) Sub-paragraph (2) shall not apply in respect of premises at which pharmaceutical services are provided by a distance selling chemist.

(4) A pharmacist shall, on request, submit a return to the Primary Care Trust setting out—

- (a) the days on which and times at which pharmaceutical services are provided at each of the premises from which he has undertaken to provide pharmaceutical services (including times at which he is providing pharmaceutical services when he is not obliged to do so by virtue of sub-paragraph (1)); and
- (b) the pharmaceutical services which he ordinarily provides at each of those premises,

but all pharmacists, if they are on a pharmaceutical list on 1st April 2005, shall supply such a return to their Primary Care Trusts by 1st July 2005 and shall state in that return if the days and times submitted represent a change to the days on which and times at which they provided pharmaceutical services at those premises prior to 1st April 2005.

(5) Where a pharmacist changes—

- (a) the days on which or times at which pharmaceutical services are to be provided at premises from which he has undertaken to provide pharmaceutical services; or
- (b) the pharmaceutical services which he is ordinarily to provide at those premises,

he shall supply the Primary Care Trust with a return informing it of the change.

(6) Where a pharmacist has submitted a return under sub-paragraph (4) or (5) in respect of any premises, or where he has set out in an application under these Regulations for inclusion in a pharmaceutical list the days on which and times at which pharmaceutical services will be provided at the premises to which the application relates if the application is granted—

- (a) he shall ensure that pharmaceutical services are provided at the premises to which the return or application relates on the days and at the times set out in the return or application (unless the return or application has been superseded by a return, or a further return, under sub-paragraph (5)); and
- (b) he shall not change—
 - (i) the days on which or the times at which pharmaceutical services are to be provided at those premises; or
 - (ii) the pharmaceutical services which he is ordinarily to provide at those premises, as set out in that return or application, for a period of at least three months after that return or application was received by the Primary Care Trust.

(7) Subject to sub-paragraph (8), where a pharmacist is prevented by illness or other reasonable cause from complying with his obligations under sub-paragraph (1), he shall, where practicable, make arrangements with one or more pharmacists or LPS chemists whose premises are situated in the neighbourhood for the provision of pharmaceutical services or local pharmaceutical services during that time.

(8) A pharmacist may make an arrangement with an LPS chemist under sub-paragraph (7) only where that LPS chemist provides local pharmaceutical services which are of a similar description as, and a similar extent to, the pharmaceutical services which he ordinarily provides.

(9) Where there is a temporary suspension in the provision of pharmaceutical services by a pharmacist for a reason beyond the control of the pharmacist, the pharmacist shall not be in breach of sub-paragraphs (1) and (2), provided that—

- (a) he notifies the Primary Care Trust of that suspension as soon as practical; and
- (b) he uses all reasonable endeavours to resume provision of pharmaceutical services as soon as is practicable.

(10) Planned refurbishment of a pharmacy is neither a “reasonable cause” for the purposes of sub-paragraph (7) nor a “reason beyond the control of the pharmacist” for the purposes of sub-paragraph (9).

(11) For the purposes of calculating the number of hours that a pharmacy is open during a week that includes Christmas Day, Good Friday or a bank holiday, it shall be deemed that the pharmacy was open on that day at the times at which it would ordinarily have been open on that day of the week.

(12) In this Part, the “additional hours” for which a pharmacist is to be required to provide pharmaceutical services are those hours during which the pharmacist would not be providing pharmaceutical services, were he subject to the condition set out in sub-paragraph (1)(a) and not the condition set out in sub-paragraph (1)(e).

Matters to be considered when issuing directions in respect of pharmacy opening hours

23.—(1) Where a Primary Care Trust issues a direction setting any days or times under this Part, it shall in doing so seek to ensure that the hours at which premises are open for the provision of pharmaceutical services are such as to ensure that pharmaceutical services are provided on such days and at such times as are necessary to meet the needs of people in the neighbourhood, or other likely users of the pharmacy, for pharmaceutical services.

(2) In considering the matters mentioned in sub-paragraph (1), the Primary Care Trust—

- (a) shall treat any local pharmaceutical services being provided in that neighbourhood at the days and times in question as if they were pharmaceutical services being so provided; and
- (b) may have regard to any pharmaceutical services that are being provided in that neighbourhood in circumstances where the pharmacist is not obliged to provide those services.

(3) The Primary Care Trust may only direct that a pharmacist may provide pharmaceutical services at premises for less than 40 hours in any week if it is satisfied that the provision of pharmaceutical services in the neighbourhood is likely to be adequate to meet the need for such services at times when the pharmacist is not providing pharmaceutical services.

(4) The Primary Care Trust may only direct that a pharmacist must provide pharmaceutical services at premises for more than 40 hours in any week where it is satisfied that he will receive reasonable remuneration in respect of the additional hours for which he is required to provide pharmaceutical services (and any additional remuneration payable under the Drug Tariff in respect of those hours is “reasonable remuneration” for these purposes).

Determination of pharmacy opening hours instigated by the Primary Care Trust

24.—(1) Where it appears to the Primary Care Trust, after consultation with or having considered the matter at the request of the Local Pharmaceutical Committee, that the days on which or times at which a pharmacy is or will be open for the provision of pharmaceutical services will not, or no longer meet, the needs of—

- (a) people in the neighbourhood; or
- (b) other likely users of his pharmacy,

for pharmaceutical services, it shall carry out an assessment as to whether to issue a direction requiring the pharmacist whose pharmacy it is to provide pharmaceutical services at the pharmacy at set times and on set days (which may include Christmas Day, Good Friday and bank holidays).

(2) Before concluding the assessment under sub-paragraph (1) the Primary Care Trust shall—

- (a) give notice to the pharmacist of any proposed changes to the days on which or times at which the pharmacy is to be open; and
- (b) allow him 30 days within which to make written representations to the Primary Care Trust about the proposed changes.

(3) After considering any representations made in accordance with sub-paragraph (2)(b), the Primary Care Trust shall—

- (a) issue a direction (which will replace any existing direction) which meets the requirements of sub-paragraphs (4) and (5);
- (b) confirm any existing direction in respect of the times at which the pharmacist must provide pharmaceutical services at the pharmacy, provided that the existing direction, whether issued under this Part or paragraph 4 of Schedule 2 to the 1992 Regulations, would meet the requirements of sub-paragraphs (4) and (5) if it were issued under this paragraph;
- (c) either—
 - (i) revoke (without replacing it) any existing direction in respect of the times at which the pharmacist must provide pharmaceutical services at the pharmacy, whether issued under this Part or paragraph 4 of Schedule 2 to the 1992 Regulations, or

(ii) in a case where there is no existing direction, issue no direction, in which case, by virtue of paragraph 22(1)(a), the pharmacy will need to be open for not less than 40 hours each week.

(4) Where a Primary Care Trust issues a direction under sub-paragraph (3) in respect of a pharmacy that is to be required to be open—

- (a) for more than 40 hours each week, it shall set out in that direction—
 - (i) the total number of hours each week for which the pharmacist shall provide pharmaceutical services at the pharmacy, and
 - (ii) as regards the additional hours for which he is to provide pharmaceutical services, the days on which and the times at which he is required to provide those services during those additional hours,but it shall not set out in that direction the days on which or times at which he is to provide pharmaceutical services during hours which are not additional hours; or
- (b) for less than 40 hours each week, it shall set out in that direction the days on which and times at which pharmaceutical services are to be provided at that pharmacy.

(5) The Primary Care Trust shall not issue a direction under sub-paragraph (3) that has the effect simply of requiring a pharmacy to be open for 40 hours each week on set days and at set times (that is, the direction must have the effect of requiring a pharmacy to be open for either more or less than 40 hours each week).

(6) The Primary Care Trust shall notify the pharmacist in writing of any direction issued or any other action taken under sub-paragraph (3), and where it sets new days on which or times at which the pharmacist is to provide pharmaceutical services at the pharmacy, it shall include with the notification a statement in writing of—

- (a) the reasons for the change; and
- (b) the pharmacist's right of appeal under paragraph (7).

(7) A pharmacist may, within 30 days of receiving notification under sub-paragraph (6), appeal in writing to the Secretary of State against any direction issued or any other action taken under sub-paragraph (3) which sets new days on which or times at which the pharmacist is to provide pharmaceutical services.

(8) The Secretary of State may, when determining an appeal, either confirm the action taken by the Primary Care Trust or take any action that the Primary Care Trust could have taken under paragraph (3).

(9) The Secretary of State shall notify the pharmacist in writing of his determination and shall in every case include with the notification a written statement of the reasons for the determination.

(10) If the days on which or times at which a pharmacist is to provide pharmaceutical services at a pharmacy have been changed in accordance with this paragraph, the pharmacist shall introduce the changes—

- (a) if he has not appealed under sub-paragraph (7), not later than 8 weeks after the date on which he receives his notification under sub-paragraph (6); or
- (b) if he has appealed under sub-paragraph (7), not later than 8 weeks after the date on which he receives his notification under sub-paragraph (9).

Determination of pharmacy opening hours instigated by the pharmacist

25.—(1) A pharmacist may apply to a Primary Care Trust for it to change the days on which or times at which he is obliged to provide pharmaceutical services at his pharmacy in a way that—

- (a) reduces the total number of hours for which the pharmacist is obliged to provide pharmaceutical services each week; or
- (b) keeps that total number of hours the same.

(2) Where a pharmacist makes an application under paragraph (1), as part of that application he shall provide the Primary Care Trust with such information as the Primary Care Trust may

reasonably request in respect of any changes to the needs of the people in the neighbourhood, or other likely users of the pharmacy, for pharmaceutical services that are material to the application.

(3) The Primary Care Trust shall determine an application under sub-paragraph (1) within 60 days of receiving it (including any information required of the applicant in accordance with paragraph (2)).

(4) In determining the application, the Primary Care Trust shall—

- (a) issue a direction (which will replace any existing direction) which meets the requirements of sub-paragraphs (5) and (6) and which has the effect of either granting the application under this paragraph or granting it only in part;
- (b) confirm any existing direction in respect of the times at which the pharmacist must provide pharmaceutical services at the pharmacy, provided that the existing direction, whether issued under this Part or paragraph 4 of Schedule 2 to the 1992 Regulations, would meet the requirements of sub-paragraphs (5) and (6);
- (c) either—
 - (i) revoke (without replacing it) any existing direction in respect of the times at which the pharmacist must provide pharmaceutical services at the pharmacy, whether issued under this Part or paragraph 4 of Schedule 2 to the 1992 Regulations, where this has the effect of granting the application under this paragraph or granting it only in part, or
 - (ii) in a case where there is no existing direction, issue no direction, in which case, by virtue of paragraph 22(1)(a), the pharmacy will need to be open for not less than 40 hours each week.

(5) Where a Primary Care Trust issues a direction under sub-paragraph (4) in respect of a pharmacy that is to be required to be open—

- (a) for more than 40 hours each week, it shall set out in that direction—
 - (i) the total number of hours each week for which the pharmacist shall provide pharmaceutical services at the pharmacy, and
 - (ii) as regards the additional hours for which he is to provide pharmaceutical services, the days on which and the times at which he is required to provide those services during those additional hours, but it shall not set out in that direction the days on which or times at which he is to provide pharmaceutical services during hours which are not additional hours; or
- (b) for less than 40 hours each week, it shall set out in that direction the days on which and times at which pharmaceutical services are to be provided at that pharmacy.

(6) The Primary Care Trust shall not issue a direction under sub-paragraph (4) that has the effect simply of requiring a pharmacy to be open for 40 hours each week on set days and at set times (that is, the direction must have the effect of requiring a pharmacy to be open for either more or less than 40 hours each week).

(7) Where the Primary Care Trust is considering taking action under sub-paragraph (4)(a) or (c)(i), it shall consult the Local Pharmaceutical Committee before determining the application.

(8) A Primary Care Trust shall notify the pharmacist in writing of any direction issued or any other action taken under sub-paragraph (4), and where this has the effect of refusing an application under this paragraph or granting it in part, it shall send the pharmacist a statement in writing setting out—

- (a) the reasons for the refusal or, as the case may be, for granting the application only in part; and
- (b) the pharmacist's right of appeal under sub-paragraph (9).

(9) A pharmacist may, within 30 days of receiving a notification pursuant to sub-paragraph (8), appeal in writing to the Secretary of State against any action under sub-paragraph (4) which has the effect of refusing an application under this paragraph or granting it only in part.

(10) The Secretary of State may, when determining an appeal, either confirm the action taken by the Primary Care Trust or take any action that the Primary Care Trust could have taken under sub-paragraph (4).

(11) The Secretary of State shall notify the pharmacist in writing of his determination and shall in every case include with the notification a written statement of the reasons for the determination.

(12) If the days on which or times at which a pharmacist is to provide pharmaceutical services at a pharmacy have been changed in accordance with this paragraph, the pharmacist shall introduce the changes—

- (a) if he has not appealed under sub-paragraph (9), not earlier than 30 days after the date on which he receives his notification under sub-paragraph (4); or
- (b) if he has appealed under sub-paragraph (9), not earlier than 30 days after the date on which he receives his notification under sub-paragraph (11).

(13) Where an application under sub-paragraph (1)—

- (a) is received by 1st July 2005; and
- (b) is in respect of a direction under paragraph 4 of Schedule 2 to the 1992 Regulations to require the applicant to provide pharmaceutical services at a pharmacy for more than 40 hours per week, and at set times and on set days,

if the Primary Care Trust fails to determine the application within 60 days of receiving it, in accordance with sub-paragraph (3), that application shall be deemed to have been granted, as from three months from the date on which the application was received by the Primary Care Trust.

(14) Where an application under sub-paragraph (1)—

- (a) is received by 1st July 2005; and
- (b) is in respect of a direction under paragraph 4 of Schedule 2 to the 1992 Regulations to require the applicant to provide pharmaceutical services at a pharmacy for more than 40 hours per week, and at set times and on set days,

until that application (including any appeal) is determined or deemed to have been granted, paragraph 22(1)(a) shall apply in respect of the application as if for “40” there were substituted “30”.

PART 4

CLINICAL GOVERNANCE, FITNESS TO PRACTISE AND COMPLAINTS

Clinical governance

26.—(1) A pharmacist shall, in connection with all the pharmaceutical services provided by him, participate, in the manner reasonably required by his Primary Care Trust, in an acceptable system of clinical governance.

(2) For these purposes a system of clinical governance is “acceptable” if it is considered acceptable by the Secretary of State and comprises the following components—

- (a) a patient and public involvement programme, which includes—
 - (i) a requirement that the pharmacist should produce in an approved manner, and make available in an appropriate manner, a practice leaflet in respect of his pharmacy,
 - (ii) a requirement that the pharmacist publicises the NHS services that are available at or from his pharmacy,
 - (iii) a requirement that the pharmacist should undertake an approved patient satisfaction survey annually, in an approved manner,
 - (iv) the pharmacist’s monitoring arrangements for drugs or appliances owed to patients but which are out of stock,
 - (v) an approved complaints system (which meets the requirements of this Part),

- (vi) a requirement that the pharmacist co-operates appropriately with local Patients' Forum visits and takes appropriate action following the outcome of such visits,
 - (vii) a requirement that the pharmacist co-operates appropriately with any reasonable inspection or review that the Primary Care Trust or any relevant statutory authority wishes to undertake, and
 - (viii) the pharmacist's monitoring arrangements in respect of his compliance with the Disability Discrimination Act 1995;
- (b) a clinical audit programme (normally of five days), which includes at least one pharmacy-based audit and one multi-disciplinary audit agreed by his Primary Care Trust in each financial year;
- (c) a risk management programme, which includes—
- (i) arrangements for ensuring that all stock is procured and handled in an appropriate way,
 - (ii) arrangements for ensuring that all equipment used in the provision of pharmaceutical services is maintained appropriately,
 - (iii) an approved incident reporting system, together with arrangements for analysing and responding to critical incidents,
 - (iv) appropriate standard operating procedures, including standard operating procedures in respect of dispensing drugs and appliances, repeatable prescriptions and providing advice and support to people caring for themselves or their families,
 - (v) appropriate waste disposal arrangements (in addition to those required under Part 2) for clinical and confidential waste,
 - (vi) a clinical governance lead person in respect of each pharmacy,
 - (vii) appropriate child protection procedures, and
 - (viii) the pharmacist's monitoring arrangements in respect of his compliance with the Health and Safety at Work etc. Act 1974;
- (d) a clinical effectiveness programme, which includes arrangements for ensuring that appropriate advice is given by a pharmacist in respect of repeatable prescriptions or to people caring for themselves or their families;
- (e) a staffing and staff management programme, which includes—
- (i) arrangement for appropriate induction for staff and locums,
 - (ii) appropriate training for all staff in respect of any role they are asked to perform,
 - (iii) arrangements for the checking of qualifications and references of all staff engaged in the provision of NHS services,
 - (iv) arrangements for identifying and supporting the development needs of all staff engaged in the provision of services as part of the health service, including continuing professional development for registered pharmacists and any necessary accreditation in respect of the provision of directed services, and
 - (v) arrangements for addressing poor performance (in conjunction with a Primary Care Trust as appropriate); and
- (f) a use of information programme, which includes—
- (i) appropriate arrangements (having regard to issues both of rights of access to information and of confidentiality) to support both health care delivery and clinical governance,
 - (ii) appropriate arrangements in respect of compliance with 'Confidentiality: the National Health Service Code of Practice'^(a),

(a) This Code of Practice is available at www.dh.gov.uk/publicationsandstatistics.

- (iii) the pharmacist's monitoring arrangements in respect of his compliance with the Data Protection Act 1998 and with regard to patient confidentiality, and
- (iv) appropriate training for staff with regard to compliance with the Data Protection Act 1998 and patient confidentiality,

and for the purposes of this sub-paragraph, "approved" means approved by the Secretary of State.

Professional Standards

27. A pharmacist shall provide pharmaceutical services and exercise any professional judgement in connection with the provision of such services in conformity with the standards generally accepted in the pharmaceutical profession.

Inducements etc.

28.—(1) A pharmacist or his staff shall not give, promise or offer to any person any gift or reward (whether by way of a share of or dividend on the profits of the business or by way of discount or rebate or otherwise) as an inducement to or in consideration of his—

- (a) presenting an order for drugs or appliances on a non-electronic prescription form or non-electronic repeatable prescription; or
- (b) nominating the pharmacist as his dispensing contractor (or one of them) in his NHS Care Record.

(2) Promising, offering or providing an auxiliary aid in relation to the supply of drugs or a home delivery service is not a gift or reward for the purposes of sub-paragraph (1).

Duty to provide information about fitness to practise matters: pharmacists on pharmaceutical lists on 1st April 2005

29.—(1) In the case of a pharmacist who is on a pharmaceutical list on 1st April 2005, subject to paragraph 31, the pharmacist and where the pharmacist is a body corporate, every director and superintendent of the pharmacist shall, by 3rd October 2005, supply in writing information to the Primary Care Trust as to whether he—

- (a) has any criminal convictions in the United Kingdom;
- (b) has accepted a police caution in the United Kingdom;
- (c) has, in summary proceedings in Scotland in respect of an offence, been the subject of an order discharging him absolutely (without proceeding to conviction);
- (d) has accepted a conditional offer under section 302 of the Criminal Procedure (Scotland) Act 1995(a) (fixed penalty: conditional offer by procurator fiscal) or agreed to pay a penalty under section 115A of the Social Security Administration Act 1992(b) (penalty as alternative to prosecution);
- (e) has been convicted elsewhere of an offence, or what would constitute a criminal offence if committed in England and Wales;
- (f) has been charged with an offence and is currently the subject of any proceedings which might lead to a conviction, which have not yet been notified to the Primary Care Trust;
- (g) has been subject to any investigation into his professional conduct by any licensing, regulatory or other body, where the outcome was adverse;
- (h) is currently subject to any investigation into his professional conduct by any licensing, regulatory or other body;

(a) 1995 c.46.

(b) 1992 c.5; section 115A was inserted by section 15 of the Social Security Administration (Fraud) Act 1997 (c.47).

- (i) is to his knowledge, or has been where the outcome was adverse, the subject of any investigation by the National Health Service Counter Fraud and Security Management Service in relation to fraud;
- (j) is the subject of any investigation by another Primary Care Trust or equivalent body, which might lead to his removal from any list or equivalent list;
- (k) is, or has been where the outcome was adverse, subject to an investigation into his professional conduct in respect of any current or previous employment; or
- (l) has been removed or contingently removed from, refused admission to, or conditionally included in, any of another Primary Care Trust's lists, or equivalent lists kept by an equivalent body, or is currently suspended from such a list, on fitness to practice grounds,

and if so, he shall give details of any investigation or proceedings which were or are to be brought, including the nature of that investigation or proceedings, where and approximately when that investigation or those proceedings took place or are to take place, and any outcome.

(2) Subject to paragraph 31, if a person to whom sub-paragraph (1) applies is, or was at the time of the originating events, a director or superintendent of a body corporate, he shall in addition and at the same time supply in writing information to the Primary Care Trust as to whether the body corporate—

- (a) has any criminal convictions in the United Kingdom;
- (b) has been convicted elsewhere of an offence, or what would constitute a criminal offence if committed in England and Wales;
- (c) is currently the subject of any proceedings which might lead to such a conviction, which have not yet been notified to the Primary Care Trust;
- (d) has been subject to any investigation into its provision of professional services by any licensing, regulatory or other body, where the outcome was adverse;
- (e) is currently subject to any investigation into its provision of professional services by any licensing, regulatory or other body;
- (f) is to his knowledge, or has been where the outcome was adverse, the subject of any investigation by the National Health Service Counter Fraud and Security Management Service in relation to fraud;
- (g) is the subject of any investigation by another Primary Care Trust or equivalent body, which might lead to its removal from any list or equivalent list; or
- (h) has been removed or contingently removed from, refused admission to, or conditionally included in, any of another Primary Care Trust's lists, or equivalent lists kept by an equivalent body, or is currently suspended from such a list, on fitness to practise grounds,

and if so, he shall give the name and registered office of the body corporate, and details of any investigation or proceedings which were or are to be brought, including the nature of the investigation or proceedings, where and approximately when that investigation or those proceedings took place or are to take place, and any outcome.

(3) A person to whom sub-paragraph (1) or (2) applies shall consent to a request being made by the Primary Care Trust to any employer or former employer or licensing or regulatory body in the United Kingdom or elsewhere, for information relating to a current investigation, or an investigation where the outcome was adverse.

(4) A person need not supply information under sub-paragraph (1)(a) to (e) or (2)(a) or (b) if that information would not be included in an enhanced criminal record certificate issued to that person by the Secretary of State under section 115(1) of the of the Police Act 1997^(a) (enhanced criminal record certificates) on the day on which that person supplies the information to the Primary Care Trust.

(a) 1997 c.50.

Duty to provide information about fitness to practise matters as they arise

30.—(1) Subject to paragraph 31, a pharmacist and where the pharmacist is a body corporate, every director and superintendent of the pharmacist shall, within 7 days of its occurrence, inform the Primary Care Trust in writing if he—

- (a) is convicted of any criminal offence in the United Kingdom;
- (b) is bound over following a criminal conviction in the United Kingdom;
- (c) accepts a police caution in the United Kingdom;
- (d) has, in summary proceedings in Scotland in respect of an offence, been the subject of an order discharging him absolutely (without proceeding to conviction);
- (e) has accepted and agreed to pay either a procurator fiscal fine under section 302 of the Criminal Procedure (Scotland) Act 1995 or a penalty under section 115A of the Social Security Administration Act 1992;
- (f) is convicted elsewhere of an offence, or what would constitute a criminal offence if committed in England and Wales;
- (g) is charged in the United Kingdom with a criminal offence, or is charged elsewhere with an offence which, if committed in England and Wales, would constitute a criminal offence;
- (h) is notified by any licensing, regulatory or other body of the outcome of any investigation into his professional conduct, and there is a finding against him;
- (i) becomes the subject of any investigation into his professional conduct by any licensing, regulatory or other body;
- (j) becomes subject to an investigation into his professional conduct in respect of any current or previous employment, or is notified of the outcome of any such investigation and any finding against him;
- (k) becomes the subject of any investigation by the National Health Service Counter Fraud and Security Management Service in relation to fraud;
- (l) becomes the subject of any investigation by another Primary Care Trust or equivalent body, which might lead to his removal from any list or equivalent list; or
- (m) is removed, contingently removed or suspended from, refused admission to, or conditionally included in any list, or equivalent list, on fitness to practise grounds,

and if so, he shall give details of any investigation or proceedings which were or are to be brought, including the nature of the investigation or proceedings, where and approximately when that investigation or those proceedings took place or are to take place, and any outcome.

(2) Subject to paragraph 31, if a person to whom paragraph (1) applies is, or was at the time of the originating events, a director or superintendent of a body corporate, he shall in addition inform the Primary Care Trust within 7 days if any such body corporate—

- (a) is convicted of any criminal offence in the United Kingdom;
- (b) is convicted elsewhere of an offence, or what would constitute a criminal offence if committed in England and Wales;
- (c) is charged in the United Kingdom with a criminal offence, or is charged elsewhere with an offence which, if committed in England and Wales, would constitute a criminal offence;
- (d) is notified by any licensing, regulatory or other body of the outcome of any investigation into its provision of professional services, and there is a finding against the body corporate;
- (e) becomes the subject of any investigation into its provision of professional services by any licensing, regulatory or other body;
- (f) becomes the subject of any investigation by the National Health Service Counter Fraud and Security Management Service in relation to any fraud or is notified of the outcome of such an investigation where it is adverse;

- (g) becomes the subject of any investigation by another Primary Care Trust or equivalent body, which might lead to its removal from any list or equivalent list; or
- (h) is removed, contingently removed or suspended from, refused admission to, or conditionally included in any list, or equivalent list, on fitness to practise grounds,

and if so, he shall give the name and registered office of the body corporate and details of any investigation or proceedings which were or are to be brought, including the nature of the investigation or proceedings, where and approximately when that investigation or those proceedings took place or are to take place, and any outcome.

(3) A person to whom sub-paragraph (1) or (2) applies shall consent to a request being made by the Primary Care Trust to any employer or former employer or licensing or regulatory body in the United Kingdom or elsewhere, for information relating to a current investigation, or an investigation where the outcome was adverse.

Home Primary Care Trust of bodies corporate

31. Where a pharmacist is a body corporate with a registered office in England, the information to be provided under paragraphs 29 and 30 may be provided only to the Primary Care Trust in which that registered office is located, if the pharmacist also provides that Primary Care Trust with details of all the other Primary Care Trusts in whose pharmaceutical lists it is included, and in these circumstances that Primary Care Trust shall pass the information on to any other Primary Care Trust—

- (a) in whose pharmaceutical list the pharmacist is included; or
- (b) to whom the pharmacist makes an application to be included in its pharmaceutical list,

that requests it.

Complaints

32. A pharmacist shall have in place arrangements for the handling and consideration of complaints about any matter connected with his provision of pharmaceutical services which are essentially the same as those set out in Part II of the National Health Service (Complaints) Regulations 2004(a).

PART 5

OTHER TERMS OF SERVICE

Directed Services

33.—(1) A pharmacist with whom a Primary Care Trust makes an arrangement for the provision of any directed services shall comply with the terms and conditions of the arrangement.

(2) Where, by virtue of regulation 13(3)(b), it is a condition of a pharmacist's inclusion in a pharmaceutical list that he provides specified directed services where requested to do so by the Primary Care Trust, that pharmacist shall comply with any such request within such period as the Primary Care Trust may specify.

Information to be supplied

34.—(1) A pharmacist shall give notice to the Primary Care Trust within 28 days (or if this is impracticable, as soon as practicable thereafter) of—

(a) S.I. 2004/1768; *see also* regulation 4 of those Regulations which imposes a requirement on Primary Care Trusts to ensure that pharmacists have such arrangements in place.

- (a) any occurrence requiring a change in the information recorded about him in the pharmaceutical list which he has not otherwise notified to him in accordance with these Regulations;
- (b) in the case of a pharmacist who is an individual, any change of his private address;
- (c) in the case of a pharmacist that is a body corporate, any change to the address of his registered office; and
- (d) any occurrence requiring his addition to or removal from the ETP list or a change in the information recorded about him in that list.

(2) A pharmacist shall give the Primary Care Trust, if it so requests, the name of any pharmacist employed by him who is responsible for dispensing a particular prescription.

(3) Subject to sub-paragraph (7), a pharmacist that is a body corporate shall (if he is on a pharmaceutical list on 1st April 2005, by 3rd October 2005) supply to his Primary Care Trust in writing the name and address of each of his directors and superintendent, and any changes to the names and addresses of each of its directors and superintendent.

(4) Subject to sub-paragraph (7), if a pharmacist or the director or the superintendent of a pharmacist that is a body corporate is himself on, or is a director or superintendent of a body corporate which is on, another NHS performers or providers list (that is, on a list other than the pharmaceutical list referred to in sub-paragraph (1)), that person shall supply in writing to the Primary Care Trust—

- (a) if he is a director or superintendent of a body corporate, the name and registered office of the body corporate on the other NHS performers or providers list; and
- (b) particulars of the other NHS performers or providers list.

(5) Subject to sub-paragraph (7), if a pharmacist or the director or superintendent of a pharmacist that is a body corporate has himself in the five years prior to 1st April 2005 been on, or has in the five years prior to 1st April 2005 been the director or superintendent of a body corporate which was when he was a director or superintendent on, another NHS performers or providers list (that is, on a list other than the pharmaceutical list referred to in sub-paragraph (1)), that person shall supply in writing to the Primary Care Trust—

- (a) the name and registered office of the body corporate on the other NHS performers or providers list; and
- (b) particulars of the NHS performers or providers list,

unless that information has already been supplied pursuant to sub-paragraph (4).

(6) Subject to sub-paragraph (7), a pharmacist or the director or superintendent of a pharmacist that is a body corporate shall inform the Primary Care Trust—

- (a) if he, or a body corporate of which he is a director or superintendent, applies to be included in any of another Primary Care Trust's NHS performers or providers lists, and of the outcome of any such application; and
- (b) if he becomes a director or superintendent of a body corporate which is on any of another Primary Care Trust's NHS performers or providers lists, or which applies to be included in such a list, and the outcome of any such application.

(7) Where a pharmacist is a body corporate with a registered office in England, the information to be provided under sub-paragraphs (3) to (6) may be provided only to the Primary Care Trust in which that registered office is located, if the pharmacist also provides that Primary Care Trust with details of all the other Primary Care Trusts in whose pharmaceutical lists it is included, and in these circumstances that Primary Care Trust shall pass the information on to any other Primary Care Trust—

- (a) in whose pharmaceutical list the pharmacist is included; or
- (b) to whom the pharmacist makes an application to be included in its pharmaceutical list,

that requests it.

(8) In this paragraph, "NHS performers or providers list" means—

- (a) a pharmaceutical list; or
- (b) any other list.

Withdrawal from pharmaceutical lists

35. Where a pharmacist intends to withdraw from a pharmaceutical list in respect of a particular pharmacy, he shall notify the Primary Care Trust of this—

- (a) at least three months in advance of that date; or
- (b) in the case of a pharmacist in respect of whom a condition is imposed by virtue of regulation 13(2)(a) as regards that pharmacy, at least six months in advance of that date,

unless it is impracticable for him to do so in which case he shall notify the Primary Care Trust as soon as it is practicable for him to do so.

Charges for drugs and refunds

36.—(1) Subject to regulations made under section 77 of the Act, all drugs, containers and appliances provided under these terms of service shall be provided free of charge.

(2) Where a pharmacist supplies a container in response to an order for drugs signed by a prescriber, or supplies an oxygen container or oxygen equipment, other than equipment specified in the Drug Tariff as not returnable to the pharmacist, the container and equipment shall remain the property of the pharmacist.

(3) Where any person who is entitled to a repayment of any charge paid under the Charges Regulations presents a pharmacist with a valid claim for the repayment within three months of the date on which the charge was paid, the pharmacist shall make the repayment.

(4) For the purposes of sub-paragraph (3), a claim for repayment is only valid if duly made on form FP57 0405 or form FP57 0403.

Inspections and access to information

37.—(1) A pharmacist shall allow persons authorised in writing by the Primary Care Trust to enter and inspect his pharmacy at any reasonable time, for the purposes of—

- (a) ascertaining whether or not the pharmacist is complying with the requirements of this Schedule;
- (b) auditing, monitoring and analysing—
 - (i) the provision made by the pharmacist, in the course of providing pharmaceutical services, for patient care and treatment, and
 - (ii) the management by the pharmacist of the pharmaceutical services he provides,

where the conditions in sub-paragraph (2) are satisfied.

(2) The conditions are that—

- (a) reasonable notice of the intended entry has been given;
- (b) the Local Pharmaceutical Committee for the area where the pharmacy is situated have been invited to be present at the inspection, where this is requested by the pharmacist;
- (c) the person authorised in writing carries written evidence of his authorisation, which he produces on request; and
- (d) he does not enter any part of the premises used solely as residential accommodation without the consent of the resident.

(3) A pharmacist shall, at the request of the Primary Care Trust or of a person authorised in writing mentioned in sub-paragraph (1), allow it or him access to any information which it or he reasonably requires—

- (a) for the purposes mentioned in sub-paragraph (1); or

- (b) in the case of the Primary Care Trust, in connection with its functions that relate to pharmaceutical services.

SCHEDULE 2

Regulation 3(b)

TERMS OF SERVICE OF DISPENSING DOCTORS

Incorporation of provisions

1. Any provisions of the following affecting the rights and obligations of dispensing doctors shall be deemed to form part of the terms of service for dispensing doctors—

- (a) the Regulations;
- (b) the Drug Tariff in so far as it lists drugs and appliances for the purposes of section 41 of the Act;
- (c) so much of Part II of the National Health Service (Service Committees and Tribunal) Regulations 1992(a) as relates to—
 - (i) the investigation of questions arising between dispensing doctors and persons receiving pharmaceutical services and other investigations to be made by the pharmaceutical discipline committee and the joint discipline committee and the action which may be taken by the Primary Care Trust as a result of such investigations, and,
 - (ii) appeals to the Secretary of State from decisions of the Primary Care Trust; and
- (d) so much of regulation 3 of the Patients' Forums (Functions) Regulations 2003(b) as relate to the entry and inspection of premises either owned or controlled by the dispensing doctor or where pharmaceutical services are provided by him.

Persons duly authorised to dispense on behalf of dispensing doctors

2. Where this Schedule imposes a requirement on a dispensing doctor in respect of an activity which he has duly authorised another person to undertake, if that other person undertakes that activity instead of the dispensing doctor—

- (a) that other person must comply with that requirement; and
- (b) that dispensing doctor must secure compliance with that requirement by that other person,

and references in this Schedule to a dispensing doctor shall be construed accordingly.

Dispensing of drugs and appliances ordered by another prescriber

3.—(1) In this paragraph, “signed” includes signature with a prescriber’s advanced electronic signature.

(2) Subject to the following provisions of this Schedule, where—

- (a) any person presents to a dispensing doctor a non-electronic prescription form which contains—
 - (i) an order for drugs, not being Scheduled drugs, or for appliances, not being restricted availability appliances, signed by a prescriber other than the dispensing doctor,
 - (ii) an order for drugs specified in Schedule 2 to the Prescription of Drugs Regulations, signed by a prescriber other than the dispensing doctor, and including the reference “SLS”, or

(a) S.I. 1992/664.

(b) S.I. 2003/2124. Regulation 3 has been amended by S.I. 2004/540, 696 and 865.

- (iii) an order for restricted availability appliances, signed by a prescriber other than the dispensing doctor and including the reference “SLS”; or
- (b) subject to sub-paragraph (4), the dispensing doctor receives from the ETP service an electronic prescription form which contains an order of a kind specified in paragraph (a)(i) to (iii) and—
 - (i) any person requests the provision of drugs or appliances in accordance with that prescription, or
 - (ii) the dispensing doctor has previously arranged with the patient that he will dispense that prescription on receipt,

and the dispensing doctor is authorised or required by virtue of Part 5 of these Regulations to provide the drugs or appliances so ordered, he shall, with reasonable promptness, provide the drugs so ordered, and such of the appliances so ordered as he supplies in the normal course of his business.

(3) Subject to the following provisions of this Part, where—

- (a) any person presents to a dispensing doctor a non-electronic repeatable prescription which contains—
 - (i) an order for drugs, not being Scheduled drugs or controlled drugs within the meaning of the Misuse of Drugs Act 1971(a), other than a drug which is for the time being specified in Schedule 4 or 5 to the Misuse of Drugs Regulations 2001(b), signed by a prescriber other than the dispensing doctor who is a repeatable prescriber,
 - (ii) an order for a drug specified in Schedule 2 to the Prescription of Drugs Regulations, not being 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 4 or 5 to the Misuse of Drugs Regulations 2001, signed by a prescriber other than the dispensing doctor who is a repeatable prescriber and including the reference “SLS”,
 - (iii) an order for appliances, not being restricted availability appliances, signed by a prescriber other than the dispensing doctor who is a repeatable prescriber, or
 - (iv) an order for a restricted availability appliance, signed by a prescriber other than the dispensing doctor who is a repeatable prescriber, and including the reference “SLS”, and also presents an associated batch issue; or
- (b) the dispensing doctor receives an electronic repeatable prescription from the ETP service which contains an order of a kind specified in paragraph (a)(i) to (iv) and—
 - (i) any person requests the provision of drugs or appliances in accordance with that repeatable prescription, or
 - (ii) the dispensing doctor has previously arranged with the patient that he will dispense that repeatable prescription on receipt,

and the dispensing doctor is authorised or required by virtue of Part 5 of these Regulations to provide the drugs or appliances so ordered, he shall, with reasonable promptness, provide the drugs so ordered, and such of the appliances so ordered as he supplies in the normal course of his business.

(4) A dispensing doctor shall not provide under an electronic prescription form 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 4 or 5 to the Misuse of Drugs Regulations 2001.

(5) For the purposes of this paragraph, a non-electronic repeatable prescription for drugs or appliances shall be taken to be presented even if the person who wishes to obtain the drugs or appliances does not present that prescription, where—

- (a) the dispensing doctor has that prescription in his possession; and

(a) 1971 c.38; see section 2(1)(a) of that Act, which defines “controlled drug” for the purposes of that Act.
 (b) S.I. 2001/3998. Schedule 4 has been amended by S.I. 2003/1432.

- (b) that person presents, or the dispensing doctor has in his possession, an associated batch issue.

(6) Drugs and listed appliances provided under this paragraph shall be provided in a suitable container.

Dispensing of drugs and appliances ordered by the dispensing doctor

4. In circumstances where paragraph 3 does not apply and subject to the following provisions of this Schedule, where a dispensing doctor is authorised or required by virtue of Part 5 of these Regulations to provide a drug or appliance to a person—

- (a) he shall record an order for the provision of any drugs or appliances which are needed for the treatment of the patient on—
 - (i) a prescription form completed in accordance with the term of a contract which gives effect to paragraph 39(3) of Schedule 6 to the GMS Regulations or an equivalent provision applying in relation to that contract, or
 - (ii) if paragraph 39A(1) of Schedule 6 to the GMS Regulations applies, an electronic prescription form;
- (b) he shall provide those drugs or appliances in a suitable container;
- (c) he shall provide for the patient a drug specified in Schedule 2 to the Prescription of Drugs Regulations only where the conditions in paragraph 42(2) of Schedule 6 to the GMS Regulations are satisfied; and
- (d) he shall 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.

Preliminary matters before providing ordered drugs or appliances

5. Before providing any drugs or appliances in accordance with paragraph 3, or in the circumstances set out in paragraph 4—

- (a) the dispensing doctor shall ask any person who makes a declaration that the patient does not have to pay the charges specified in regulation 4(1) of the Charges Regulations by virtue of either—
 - (i) entitlement to exemption under regulation 8(1) of the Charges Regulations, or
 - (ii) entitlement to remission of charges under regulation 5 of the Remission of Charges Regulations,

to produce satisfactory evidence of such entitlement, unless the declaration is in respect of entitlement to exemption by virtue of regulation 8 of the Charges Regulations or in respect of entitlement to remission by virtue of regulation 4(2)(e), (j) or (k) of the Remission of Charges Regulations, and at the time of the declaration the dispensing doctor has such evidence available to him;

- (b) if, in the case of a non-electronic prescription form or non-electronic repeatable prescription, no satisfactory evidence, as required by sub-paragraph (a), is produced to the dispensing doctor, the dispensing doctor shall endorse the form on which the declaration is made to that effect; and
- (c) in the case of an electronic prescription, the dispensing doctor shall transmit to the ETP service—
 - (i) in a case where exemption from or remission of charges is claimed for all or some of the items included in the prescription, a record of—
 - (aa) the exemption category specified in regulation 7(1) of the Charges Regulations or the ground for remission under regulation 5 of the Remission of Charges Regulations which it is claimed applies to the case; and
 - (bb) whether or not satisfactory evidence was produced to him as required by sub-paragraph (a),

- (ii) in any case where a charge is due, confirmation that the relevant charge was paid, and
- (iii) in a case of a prescription for or including contraceptive substances, confirmation that no charge was payable in respect of those substances.

Provision of Scheduled drugs

6.—(1) Subject to sub-paragraph (2), a dispensing doctor shall not provide for a patient any Scheduled drug, except that, where he or an independent prescriber has ordered a drug which has an appropriate non-proprietary name either by the name or by its formula, he may provide a drug which has the same specification notwithstanding that it is 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).

(2) Nothing in this Schedule shall prevent a doctor providing, otherwise than under pharmaceutical services, a Scheduled drug or a restricted availability appliance for a patient.

Refusal to provide drugs or appliances ordered

7.—(1) A dispensing doctor may refuse to provide the drugs or appliances ordered on a prescription form or repeatable prescription where—

- (a) the dispensing doctor reasonably believes that it is not a genuine order for the person named on the prescription form or the repeatable prescription (for example because he reasonably believes it has been stolen or forged); or
- (b) it appears to the dispensing doctor that there is an error on the prescription form or on the repeatable prescription or, in the case of a non-electronic repeatable prescription, its associated batch issue (including a clinical error made by the prescriber) or that, in the circumstances, providing the drugs or appliances would be contrary to the dispensing doctor's clinical judgement.

(2) A dispensing doctor may refuse to provide the drugs or appliances ordered on a prescription form or repeatable prescription, or which he is otherwise authorised or required to provide by virtue of Part 5 of these Regulations, where—

- (a) the dispensing doctor or other persons on the premises are subjected to or threatened with violence by the person presenting the prescription form or repeatable prescription or requesting the provision of drugs or appliances in accordance with an electronic prescription form or a repeatable prescription, or by any person accompanying that person; or
- (b) the person presenting the prescription form or repeatable prescription or requesting the provision of drugs or appliances in accordance with an electronic prescription form or a repeatable prescription, or any other person accompanying that person, commits or threatens to commit a criminal offence.

(3) A dispensing doctor shall refuse to provide drugs or appliances ordered on a repeatable prescription where—

- (a) he has no record of that prescription;
- (b) he does not, in the case of a non-electronic repeatable prescription, have any associated batch issue and it is not presented to him;
- (c) it is not signed by a repeatable prescriber;
- (d) to do so would not be in accordance with any intervals specified in the prescription;
- (e) it would be the first time a drug or appliance had been provided pursuant to the prescription and the prescription was signed (whether electronically or otherwise) more than six months previously;
- (f) if the repeatable prescription was signed (whether electronically or otherwise) more than one year previously;

- (g) the expiry date on the repeatable prescription has passed; or
- (h) where he has been informed by the repeatable prescriber that the prescription is no longer required.

(4) Where a patient requests the supply of drugs or appliances ordered on a repeatable prescription (other than on the first occasion that he makes such a request), a dispensing doctor shall only provide the drugs or appliances ordered if he is satisfied—

- (a) that the patient to whom the prescription relates—
 - (i) is taking or using, and is likely to continue to take or use, the drug or appliance appropriately, and
 - (ii) is not suffering from any side effects of the treatment which indicates the need or desirability of reviewing the patient's treatment;
- (b) that the medication regimen of the patient to whom the prescription relates has altered in a way which indicates the need or desirability of reviewing the patient's treatment; and
- (c) there have been no changes to the health of the patient to whom the prescription relates which indicate the need or desirability of reviewing the patient's treatment.

Fees and charges

8.—(1) The terms of a GMS contract giving effect to regulation 24 of, and Schedule 5 to, the GMS Regulations (fees and charges) apply in respect of the provision of any drugs or appliances by a dispensing doctor as they apply in respect of prescriptions for drugs and appliances.

(2) Where a dispensing doctor provides a drug or appliance under pharmaceutical services—

- (a) in accordance with this Schedule; and
- (b) had the drug or appliance been provided by a contractor providing dispensing services under a GMS contract, the contractor would have been entitled to a payment in respect of the drug or appliance by virtue of directions given by the Secretary of State under section 28T of the Act,

the Primary Care Trust shall credit him with the payment.

Complaints procedures

9.—(1) Where a dispensing doctor—

- (a) is a GMS contractor, or is engaged or employed by a GMS contractor, the complaints procedure established in accordance with the terms of a GMS contract which give effect to paragraph 92 of Schedule 6 to the GMS Regulations;
- (b) is a PMS contractor, or is engaged or employed by a PMS contractor, the complaints procedure established in accordance with the terms of a PMS agreement which give effect to paragraph 86 of Schedule 5 to the PMS Regulations;
- (c) is an APMS contractor, or is engaged or employed by an APMS contractor, the complaints procedure established by the relevant APMS contract to deal with complaints in relation to the provision of primary medical services;
- (d) is employed or engaged by a Primary Care Trust for the purposes of providing services within a PCTMS practice, the complaints procedure established by that PCTMS practice to deal with complaints in relation to the provision of primary medical services,

shall apply in relation to any matter reasonably connected with the provision of pharmaceutical services as it applies as respects to services provided under that contract or agreement, or within that practice.

(2) Accordingly, the term of any relevant GMS contract which gives effect to paragraph 97 of Schedule 6 to the GMS Regulations or the equivalent provision in the PMS Regulations also applies in relation to complaints about such matters.

Inspections and access to information

10.—(1) A dispensing doctor shall allow persons authorised in writing by the Primary Care Trust to enter and inspect any premises he uses for the provision of pharmaceutical services at any reasonable time, for the purposes of—

- (a) ascertaining whether or not the dispensing doctor is complying with the requirements of this Schedule;
- (b) auditing, monitoring and analysing—
 - (i) the provision made by the dispensing doctor, in the course of providing pharmaceutical services, for patient care and treatment, and
 - (ii) the management by the dispensing doctor of the pharmaceutical services he provides,

where the conditions in sub-paragraph (2) are satisfied.

(2) The conditions are that—

- (a) reasonable notice of the intended entry has been given;
- (b) the Local Pharmaceutical Committee for the area where the premises are situated have been invited to be present at the inspection, where this is requested by the dispensing doctor;
- (c) the person authorised in writing carries written evidence of his authorisation, which he produces on request; and
- (d) he does not enter any part of the premises used solely as residential accommodation without the consent of the resident.

(3) A dispensing doctor shall, at the request of the Primary Care Trust or of a person authorised in writing mentioned in sub-paragraph (1), allow it or him access to any information which it or he reasonably requires—

- (a) for the purposes mentioned in sub-paragraph (1); or
- (b) in the case of the Primary Care Trust, in connection with its functions that relate to pharmaceutical services.

SCHEDULE 3

Regulation 3(c)

TERMS OF SERVICE OF SUPPLIERS OF APPLIANCES

Incorporation of provisions

1. Any provisions of the following affecting the rights and obligations of suppliers of appliances shall be deemed to form part of the terms of service for suppliers of appliances—

- (a) the Regulations;
- (b) the Drug Tariff in so far as it lists appliances for the purposes of section 41 of the Act;
- (c) so much of Part II of the National Health Service (Service Committees and Tribunal) Regulations 1992^(a) as relates to—
 - (i) the investigation of questions arising between suppliers of appliances and persons receiving pharmaceutical services and other investigations to be made by the pharmaceutical discipline committee and the joint discipline committee and the action which may be taken by the Primary Care Trust as a result of such investigations, and
 - (ii) appeals to the Secretary of State from decisions of the Primary Care Trust; and

^(a) S.I. 1992/664.

- (d) so much of regulation 3 of the Patients' Forums (Functions) Regulations 2003^(a) as relate to the entry and inspection of premises either owned or controlled by the supplier of appliances or where pharmaceutical services are provided by him.

Division of responsibilities between individuals and corporate bodies

2.—(1) To the extent that this Schedule imposes a requirement on a supplier of appliances in respect of an activity which could only, or would normally, be undertaken by a natural person—

- (a) if the supplier of appliances is a registered pharmacist—
 - (i) that registered pharmacist must comply with that requirement, or
 - (ii) if he employs or engages a registered pharmacist in connection with the provision of pharmaceutical services, that registered pharmacist must either comply with that requirement or secure compliance with that requirement by a person whom he employs or engages; and
- (b) if the supplier of appliances is not a natural person, that supplier of appliances must secure compliance with that requirement by a person whom he employs or engages,

and references in this Schedule to a supplier of appliances shall be construed accordingly.

(2) Where this Schedule imposes a requirement on the director of a body corporate that is included in a pharmaceutical list, breach of that requirement shall be deemed to be a breach by the body corporate of its terms of service.

Dispensing services

3. A supplier of appliances shall, to the extent that paragraphs 4 to 7 require and in the manner described in those paragraphs, provide proper and sufficient appliances to persons presenting prescriptions for appliances by health care professionals in pursuance of their functions in the health service, the Scottish health service or the Northern Ireland health service.

Dispensing of appliances

4.—(1) In this paragraph, “signed” includes signature with a prescriber’s electronic signature.

(2) Subject to paragraphs 5 to 7, where—

- (a) any person presents a non-electronic prescription form which contains—
 - (i) an order for an appliance, not being a restricted availability appliance, signed by a prescriber, or
 - (ii) an order for a restricted availability appliance, signed by a prescriber and including the reference “SLS”; or
- (b) a supplier of appliances receives from the ETP service an electronic prescription form which contains an order of a kind specified in paragraph (a)(i) and (ii) and—
 - (i) any person requests the provision of an appliance in accordance with that prescription, or
 - (ii) the supplier of appliances has previously arranged with the patient that he will dispense that prescription on receipt,

a supplier of appliances shall, with reasonable promptness, provide the appliance so ordered if he supplies it in the normal course of his business.

(a) S.I. 2003/2124. Regulation 3 has been amended by S.I. 2004/540, 696 and 865.

Preliminary matters before providing appliances

5.—(1) If the person presenting the non-electronic prescription form or requesting the provision of an appliance in accordance with an electronic prescription form asks the supplier of appliances to do so—

- (a) the supplier of appliances shall give an estimate of the time when the appliance will be ready; and
- (b) if it is not ready by then, the supplier of appliances shall give a revised estimate of the time when it will be ready (and so on).

(2) Before providing an appliance in accordance with a prescription form—

- (a) the supplier of appliances shall ask any person who makes a declaration that the person named on the prescription form does not have to pay the charges specified in regulation 3(1) or (1A) of the Charges Regulations by virtue of either—
 - (i) entitlement to exemption under regulation 7(1) of the Charges Regulations, or
 - (ii) entitlement to remission of charges under regulation 5 of the Remission of Charges Regulations,

to produce satisfactory evidence of such entitlement, unless the declaration is in respect of entitlement to exemption by virtue of sub-paragraph (a), (c), (d), (e), (f) or (g) of regulation 7(1) of the Charges Regulations or in respect of entitlement to remission by virtue of regulation 5(1)(e) or (2) of the Remission of Charges Regulations, and at the time of the declaration the supplier of appliances already has such evidence available to him;

- (b) if, in the case of a non-electronic prescription form, no satisfactory evidence, as required by sub-paragraph (a), is produced to the supplier of appliances, the supplier of appliances shall endorse the form on which the declaration is made to that effect; and
- (c) in the case of an electronic prescription form, the supplier of appliances shall transmit to the ETP service—
 - (i) in a case where exemption from or remission of charges is claimed, a record of—
 - (aa) the exemption category specified in regulation 7(1) of the Charges Regulations or the ground for remission under regulation 5 of the Remission of Charges Regulations which it is claimed applies to the case; and
 - (bb) whether or not satisfactory evidence was produced to him as required by sub-paragraph (a), and
 - (ii) in any case where a charge is due, confirmation that the relevant charge was paid.

Providing appliances

6.—(1) Where a supplier of appliances is presented with a non-electronic prescription form or receives a prescription form from the ETP service, the supplier of appliances shall only provide the drugs or appliances so ordered—

- (a) if the prescription form or repeatable prescription is duly signed and completed as described in paragraph 4; and
- (b) in accordance with the order on the prescription form,

subject to any regulations in force under the Weights and Measures Act 1985^(a) and the following provisions of this Part.

(2) If the order is for an appliance of a type requiring measuring and fitting by the supplier of appliances (for example a truss) the supplier of appliances shall make all necessary arrangements for—

- (a) measuring the person named on the prescription form for the appliance; and

(a) 1985 c.72.

(b) fitting the appliance.

(3) If the order is for an appliance included in the Drug Tariff, the British National Formulary (including any Appendix published as part of that Formulary), the Dental Practitioner's Formulary, the European Pharmacopoeia or the British Pharmaceutical Codex, the appliance provided shall comply with the standard or formula specified therein.

Refusal to provide appliances ordered

7. A supplier of appliances may refuse to provide an appliance ordered on a prescription form where—

- (a) the supplier of appliances reasonably believes that it is not a genuine order for the person named on the prescription form (for example because he reasonably believes it has been stolen or forged);
- (b) it appears to the supplier of appliances that there is an error on the prescription form (including a clinical error made by the prescriber);
- (c) the supplier of appliances or other persons on the premises are subjected to or threatened with violence by the person presenting the prescription form or requesting the provision of appliances in accordance with an electronic prescription form or by any person accompanying that person; or
- (d) the person presenting the prescription form or requesting the provision of appliances in accordance with an electronic prescription form or any other person accompanying that person, commits or threatens to commit a criminal offence.

Further activities to be carried out in connection with the provision of dispensing services

8. In connection with the services provided under paragraph 3, a supplier of appliances shall—

- (a) ensure that appropriate advice is given to patients about any appliances provided to them—
 - (i) to enable them to utilise the appliances appropriately, and
 - (ii) to meet the patient's reasonable needs for general information about the appliances;
- (b) provide appropriate advice to patients to whom they provide appliances on the safe keeping of the appliances;
- (c) provide a patient with a written note of any appliance which is owed, and inform the patient when it is expected that the appliance will become available;
- (d) keep and maintain records—
 - (i) of appliances provided, where it is necessary or desirable to do so in order to facilitate the continued care of the patient,
 - (ii) in appropriate cases, of advice given and any interventions or referrals made, and
 - (iii) of notes provided under sub-paragraph (c); and
- (e) if he provides an appliance under an electronic prescription form, provide the patient, if he so requests, with a written record of the appliances ordered on that prescription.

Additional requirements in relation to electronic prescribing

9.—(1) A supplier of appliances shall, if requested to do so by any person—

- (a) explain to him the ETP service, whether or not it is a service which is available through him; and
- (b) where the ETP service is not available through him, provide him with the names of at least two suppliers of appliances through whom the ETP service is available, if these details are known to the supplier of appliances.

(2) Where the ETP service is available through him, the supplier of appliances shall, if requested to do so by any person, enter in that person's NHS Care Record—

- (a) where the person does not have a nominated dispensing contractor, the dispensing contractor chosen by that person; and
- (b) where the person does have a nominated dispensing contractor—
 - (i) a replacement dispensing contractor, or
 - (ii) a further dispensing contractor,chosen by that person.

(3) Sub-paragraph (2)(b)(ii) shall not apply if the number of nominated dispensing contractors would thereby exceed the maximum number permitted by the ETP service.

(4) Regulation 72(a) to (c) shall apply to a request under this paragraph as it applies to an application to a chemist for pharmaceutical services.

Opening hours: general

10.—(1) A supplier of appliances shall ensure that pharmaceutical services are provided at each of the premises from which he has undertaken to provide pharmaceutical services—

- (a) for not less than 30 hours each week;
- (b) for not less than 100 hours each week, in the case of premises in respect of which the condition imposed by regulation 13(2)(a) applies as regards the supplier of appliances' inclusion in a pharmaceutical list;
- (c) if his Primary Care Trust, or on appeal the Secretary of State, has directed (either under this Schedule or paragraph 4 of Schedule 2 to the 1992 Regulations) that he may provide pharmaceutical services at the premises for fewer than 30 hours per week, provided that he provides those services at set times and on set days, at the times and on the days so set;
- (d) if his Primary Care Trust, or on appeal the Secretary of State, has directed under paragraph 4 of Schedule 2 to the 1992 Regulations, that he must provide pharmaceutical services at the premises for more than 30 hours per week, and at set times and on set days, at the times and on the days so set; or
- (e) if his Primary Care Trust, or on appeal the Secretary of State, has directed under this Schedule that he must provide pharmaceutical services at the premises for more than 30 hours each week—
 - (i) for the total number of hours each week required by virtue of that direction, and
 - (ii) as regards the additional hours for which he is required to provide pharmaceutical services by virtue of that direction, at the days on which and times at which he is required to provide pharmaceutical services during those additional hours, as set out in that direction,

but a Primary Care Trust may, in appropriate circumstances, agree a temporary suspension of services for a set period, where it has received three months notice of the proposed suspension.

(2) At each of the premises from which a supplier of appliances has undertaken to provide pharmaceutical services, a supplier of appliances shall exhibit a notice specifying the days on which and times at which the premises are open for the provision of appliances.

(3) A supplier of appliances shall, on request, submit a return to the Primary Care Trust setting out—

- (a) the days on which and times at which pharmaceutical services are provided at each of the premises from which he has undertaken to provide pharmaceutical services (including times at which he is providing pharmaceutical services when he is not obliged to do so by virtue of sub-paragraph (1)); and
- (b) the pharmaceutical services which he ordinarily provides at each of those premises.

(4) Where a supplier of appliances changes—

- (a) the days on which or times at which pharmaceutical services are to be provided at premises from which he has undertaken to provide pharmaceutical services; or
- (b) the pharmaceutical services which he is ordinarily to provide at those premises,

he shall supply the Primary Care Trust with a return informing it of the change.

(5) Subject to sub-paragraph (6), where a supplier of appliances is prevented by illness or other reasonable cause from complying with his obligations under sub-paragraph (1), he shall, where practicable, make arrangements with one or more suppliers of appliances, pharmacists or LPS chemists whose premises are situated in the neighbourhood for the provision of pharmaceutical services or local pharmaceutical services during that time.

(6) A supplier of appliances may make an arrangement with an LPS chemist under sub-paragraph (5) only where that LPS chemist provides local pharmaceutical services which are of a similar description as, and a similar extent to, the pharmaceutical services which he ordinarily provides.

(7) Where there is a temporary suspension in the provision of pharmaceutical services by a supplier of appliances for a reason beyond the control of the supplier of appliances, the supplier of appliances shall not be in breach of sub-paragraphs (1) and (2), provided that—

- (a) he notifies the Primary Care Trust of that suspension as soon as practical; and
- (b) he uses all reasonable endeavours to resume provision of pharmaceutical services as soon as is practicable.

(8) Planned refurbishment of premises is neither a “reasonable cause” for the purposes of sub-paragraph (5) nor a “reason beyond the control of the supplier of appliances” for the purposes of sub-paragraph (7).

(9) For the purposes of calculating the number of hours that premises are open during a week that includes Christmas Day, Good Friday or a bank holiday, it shall be deemed that the premises were open on that day at the times at which they would ordinarily have been open on that day of the week.

(10) In this Schedule, the “additional hours” for which a supplier of appliances is to be required to provide pharmaceutical services are those hours during which the supplier of appliances would not be providing pharmaceutical services, were he subject to the condition set out in sub-paragraph (1)(a) and not the condition set out in sub-paragraph (1)(e).

Matters to be considered when issuing directions in respect of opening hours

11.—(1) Where a Primary Care Trust issues a direction setting any days or times under this Schedule, it shall in doing so seek to ensure that the hours at which premises are open for the provision of pharmaceutical services are such as to ensure that pharmaceutical services are provided on such days and at such times as are necessary to meet the needs of people in the neighbourhood, or other likely users of the premises, for pharmaceutical services.

(2) In considering the matters mentioned in sub-paragraph (1), the Primary Care Trust—

- (a) shall treat any local pharmaceutical services being provided in that neighbourhood at the days and times in question as if they were pharmaceutical services being so provided; and
- (b) may have regard to any pharmaceutical services that are being provided in that neighbourhood in circumstances where the person providing the services is not obliged to provide those services.

(3) The Primary Care Trust may only direct that a supplier of appliances may provide pharmaceutical services at premises for less than 30 hours in any week if it is satisfied that the arrangements for the supply of appliances in the neighbourhood is likely to be adequate to meet the need for such services at times when the supplier of appliances is not providing pharmaceutical services.

(4) A Primary Care Trust may only direct that a supplier of appliances must provide pharmaceutical services at premises for more than 30 hours in any week if it is satisfied that it will receive reasonable remuneration in respect of the additional hours for which he is required to

provide pharmaceutical services (and any additional remuneration payable under the Drug Tariff in respect of those hours is “reasonable remuneration” for these purposes).

Determination of opening hours instigated by the Primary Care Trust

12.—(1) Where it appears to the Primary Care Trust, after consultation with or having considered the matter at the request of the Local Pharmaceutical Committee, that the days on which or times at which premises are or will be open for the supplying of appliances will not, or no longer meet, the needs of—

- (a) people in the neighbourhood; or
- (b) other likely users of his premises,

for the supply of appliances, it may carry out an assessment as to whether to issue a direction requiring the supplier of appliances to provide pharmaceutical services at the premises at set times and on set days (which may include Christmas Day, Good Friday and bank holidays).

(2) Before concluding the assessment under sub-paragraph (1) the Primary Care Trust shall—

- (a) give notice to the supplier of appliances of any proposed changes to the days on which or times at which the premises are to be open; and
- (b) allow him 60 days within which to make written representations to the Primary Care Trust about the proposed changes.

(3) After considering any representations made in accordance with sub-paragraph (2)(b), the Primary Care Trust shall—

- (a) issue a direction (which will replace any existing direction) which meets the requirements of sub-paragraphs (4) and (5);
- (b) confirm any existing direction in respect of the times at which the supplier of appliances must provide pharmaceutical services at the premises, provided that the existing direction, whether issued under this Schedule or paragraph 4 of Schedule 2 to the 1992 Regulations, would meet the requirements of sub-paragraphs (4) and (5) if it were issued under this paragraph;
- (c) either—
 - (i) revoke (without replacing it) any existing direction in respect of the times at which the supplier of appliances must provide pharmaceutical services at the premises, whether issued under this Schedule or paragraph 4 of Schedule 2 to the 1992 Regulations, or
 - (ii) in a case where there is no existing direction, issue no direction, in which case, by virtue of paragraph 10(1)(a), the premises will need to be open for not less than 30 hours each week.

(4) Where a Primary Care Trust issues a direction under sub-paragraph (3) in respect of premises that are to be required to be open—

- (a) for more than 30 hours each week, it shall set out in that direction—
 - (i) the total number of hours each week for which the supplier of appliances shall provide pharmaceutical services at the premises, and
 - (ii) as regards the additional hours for which he is to provide pharmaceutical services, the days on which and the times at which he is required to provide those services during those additional hours,

but it shall not set out in that direction the days on which or times at which he is to provide pharmaceutical services during hours which are not additional hours; or

- (b) for less than 30 hours each week, it shall set out in that direction the days on which and times at which pharmaceutical services are to be provided at those premises.

(5) The Primary Care Trust shall not issue a direction under sub-paragraph (3) that has the effect simply of requiring premises to be open for 30 hours each week on set days and at set times (that

is, the direction must have the effect of requiring premises to be open for either more or less than 30 hours each week).

(6) The Primary Care Trust shall notify the supplier of appliances in writing of any direction issued or any other action taken under sub-paragraph (3), and where it sets new days on which or times at which the supplier of appliances is to provide pharmaceutical services at the premises, it shall include with the notification a statement in writing of—

- (a) the reasons for the change; and
- (b) the supplier of appliances' right of appeal under paragraph (7).

(7) A supplier of appliances may, within 30 days of receiving notification under sub-paragraph (6), appeal in writing to the Secretary of State against any direction issued or any other action taken under sub-paragraph (3) which sets new days on which or times at which the supplier of appliances is to provide pharmaceutical services.

(8) The Secretary of State may, when determining an appeal, either confirm the action taken by the Primary Care Trust or take any action that the Primary Care Trust could have taken under paragraph (3).

(9) The Secretary of State shall notify the supplier of appliances in writing of his determination and shall in every case include with the notification a written statement of the reasons for the determination.

(10) If the days on which or times at which a supplier of appliances is to provide pharmaceutical services at the premises have been changed in accordance with this paragraph, the supplier of appliances shall introduce the changes—

- (a) if he has not appealed under sub-paragraph (7), not later than 8 weeks after the date on which he receives his notification under sub-paragraph (6); or
- (b) if he has appealed under sub-paragraph (7), not later than 8 weeks after the date on which he receives his notification under sub-paragraph (9).

Determination of opening hours instigated by the supplier of appliances

13.—(1) A supplier of appliances may apply to a Primary Care Trust for it to change the days on which or times at which he is obliged to provide pharmaceutical services at his premises, in a way that—

- (a) reduces the total number of hours for which the supplier of appliances is obliged to provide pharmaceutical services each week; or
- (b) keeps that total number of hours the same.

(2) Where a supplier of appliances makes an application under sub-paragraph (1), as part of that application he shall provide the Primary Care Trust with such information as the Primary Care Trust may reasonably request in respect of any changes to the needs of the people in the neighbourhood, or other likely users of the premises, for pharmaceutical services that are material to the application.

(3) The Primary Care Trust shall determine an application under sub-paragraph (1) within 60 days of receiving it (including any information required of the applicant in accordance with sub-paragraph (2)).

(4) In determining the application, the Primary Care Trust shall—

- (a) issue a direction (which will replace any existing direction) which meets the requirements of sub-paragraphs (5) and (6) and which has the effect of either granting the application under this paragraph or granting it only in part;
- (b) confirm any existing direction in respect of the times at which the supplier of appliances must provide pharmaceutical services at the premises, provided that the existing direction, whether issued under this Schedule or paragraph 4 of Schedule 2 to the 1992 Regulations, would meet the requirements of sub-paragraphs (5) and (6); or
- (c) either—

(i) revoke (without replacing it) any existing direction in respect of the times at which the supplier of appliances must provide pharmaceutical services at the premises, whether issued under this Schedule or paragraph 4 of Schedule 2 to the 1992 Regulations, where this has the effect of granting the application under this paragraph or granting it only in part, or

(ii) in a case where there is no existing direction, issue no direction,

in which case, by virtue of paragraph 10(1)(a), the premises will need to be open for not less than 30 hours each week.

(5) Where a Primary Care Trust issues a direction under sub-paragraph (4) in respect of premises that are to be required to be open—

(a) for more than 30 hours each week, it shall set out in that direction—

(i) the total number of hours each week for which the supplier of appliances shall provide pharmaceutical services at the premises, and

(ii) as regards the additional hours for which he is to provide pharmaceutical services, the days on which and the times at which he is required to provide those services during those additional hours,

but it shall not set out in that direction the days on which or times at which he is to provide pharmaceutical services during hours which are not additional hours; or

(b) for less than 30 hours each week, it shall set out in that direction the days on which and times at which pharmaceutical services are to be provided at those premises.

(6) The Primary Care Trust shall not issue a direction under sub-paragraph (4) that has the effect simply of requiring premises to be open for 30 hours each week on set days and at set times (that is, the direction must have the effect of requiring premises to be open for either more or less than 30 hours each week).

(7) Where the Primary Care Trust is considering taking action under sub-paragraph (4)(a) or (c)(i), it shall consult the Local Pharmaceutical Committee before determining the application.

(8) A Primary Care Trust shall notify the supplier of appliances in writing of any direction issued or any other action taken under sub-paragraph (4), and where this has the effect of refusing an application under this paragraph or granting it in part, it shall send the supplier of appliances a statement in writing setting out—

(a) the reasons for the refusal or, as the case may be, for granting the application only in part; and

(b) the supplier of appliances' right of appeal under sub-paragraph (9).

(9) A supplier of appliances may, within 30 days of receiving a notification pursuant to sub-paragraph (8), appeal in writing to the Secretary of State against any action under sub-paragraph (4) which has the effect of refusing an application under this paragraph or granting it only in part.

(10) The Secretary of State may, when determining an appeal, either confirm the action taken by the Primary Care Trust or take any action that the Primary Care Trust could have taken under sub-paragraph (4).

(11) The Secretary of State shall notify the supplier of appliances in writing of his determination and shall in every case include with the notification a written statement of the reasons for the determination.

(12) If the days on which or times at which the supplier of appliances is to provide pharmaceutical services at the premises have been changed in accordance with this paragraph, the supplier of appliances shall introduce the changes—

(a) if he has not appealed under sub-paragraph (9), not earlier than 30 days after the date on which he receives his notification under sub-paragraph (4); or

(b) if he has appealed under sub-paragraph (9), not earlier than 30 days after the date on which he receives his notification under sub-paragraph (11).

Professional Standards

14. A supplier of appliances shall provide pharmaceutical services and exercise any professional judgment in connection with the provision of such services in conformity with the standards generally accepted in the pharmaceutical profession.

Inducements etc.

15.—(1) A supplier of appliances or his staff shall not give, promise or offer to any person any gift or reward (whether by way of a share of or dividend on the profits of the business or by way of discount or rebate or otherwise) as an inducement to or in consideration of his—

- (a) presenting an order for appliances on a prescription form; or
- (b) nominating the supplier of appliances as his dispensing contractor (or one of them) in his NHS Care Record.

(2) Promising, offering or providing a home delivery service is not a gift or reward for the purposes of sub-paragraph (1).

Duty to provide information about fitness to practise matters: suppliers of appliances on pharmaceutical lists on 1st April 2005

16.—(1) In the case of a supplier of appliances who is on a pharmaceutical list on 1st April 2005, subject to paragraph 18, the supplier of appliances, and where the supplier of appliances is a body corporate every director of the supplier of appliances, shall, by 3rd October 2005, supply in writing information to the Primary Care Trust as to whether he—

- (a) has any criminal convictions in the United Kingdom;
- (b) has accepted a police caution in the United Kingdom;
- (c) has, in summary proceedings in Scotland in respect of an offence, been the subject of an order discharging him absolutely (without proceeding to conviction);
- (d) has accepted a conditional offer under section 302 of the Criminal Procedure (Scotland) Act 1995^(a) (fixed penalty: conditional offer by procurator fiscal) or agreed to pay a penalty under section 115A of the Social Security Administration Act 1992^(b) (penalty as alternative to prosecution);
- (e) has been convicted elsewhere of an offence, or what would constitute a criminal offence if committed in England and Wales;
- (f) has been charged with an offence and is currently the subject of any proceedings which might lead to such a conviction, which have not yet been notified to the Primary Care Trust;
- (g) has been subject to any investigation into his professional conduct by any licensing, regulatory or other body, where the outcome was adverse;
- (h) is currently subject to any investigation into his professional conduct by any licensing, regulatory or other body;
- (i) is to his knowledge, or has been where the outcome was adverse, the subject of any investigation by the National Health Service Counter Fraud and Security Management Service in relation to fraud;
- (j) is the subject of any investigation by another Primary Care Trust or equivalent body, which might lead to his removal from any list or equivalent list;
- (k) is, or has been where the outcome was adverse, subject to an investigation into his professional conduct in respect of any current or previous employment; or

(a) 1995 c.46.

(b) 1992 c.5; section 115A was inserted by section 15 of the Social Security Administration (Fraud) Act 1997 (c.47).

(1) has been removed or contingently removed from, refused admission to, or conditionally included in, any of another Primary Care Trust's lists, or equivalent lists kept by an equivalent body, or is currently suspended from such a list, on fitness to practise grounds and if so, he shall give details of any investigation or proceedings which were or are to be brought, including the nature of that investigation or proceedings, where and approximately when that investigation or those proceedings took place or are to take place, and any outcome.

(2) Subject to paragraph 18, if a person to whom sub-paragraph (1) applies is, or was at the time of the originating events, a director of a body corporate, he shall in addition and at the same time supply in writing information to the Primary Care Trust as to whether the body corporate—

- (a) has any criminal convictions in the United Kingdom;
- (b) has been convicted elsewhere of an offence, or what would constitute a criminal offence if committed in England and Wales;
- (c) is currently the subject of any proceedings which might lead to such a conviction, which have not yet been notified to the Primary Care Trust;
- (d) has been subject to any investigation into its provision of professional services by any licensing, regulatory or other body, where the outcome was adverse;
- (e) is currently subject to any investigation into its provision of professional services by any licensing, regulatory or other body;
- (f) is to his knowledge, or has been where the outcome was adverse, the subject of any investigation by the National Health Service Counter Fraud and Security Management Service in relation to fraud;
- (g) is the subject of any investigation by another Primary Care Trust or equivalent body, which might lead to its removal from any list or equivalent list; or
- (h) has been removed or contingently removed from, refused admission to, or conditionally included in, any of another Primary Care Trust's lists, or equivalent lists kept by an equivalent body, or is currently suspended from such a list, on fitness to practise grounds,

and if so, he shall give the name and registered office of the body corporate, and details of any investigation or proceedings which were or are to be brought, including the nature of the investigation or proceedings, where and approximately when that investigation or those proceedings took place or are to take place, and any outcome.

(3) A person to whom sub-paragraph (1) or (2) applies shall consent to a request being made by the Primary Care Trust to any employer or former employer or licensing or regulatory body in the United Kingdom or elsewhere, for information relating to a current investigation, or an investigation where the outcome was adverse.

(4) A person need not supply information under sub-paragraph (1)(a) to (e) or (2)(a) or (b) if that information would not be included in an enhanced criminal record certificate issued to that person by the Secretary of State under section 115(1) of the of the Police Act 1997^(a) (enhanced criminal record certificates) on the day on which that person supplies the information to the Primary Care Trust.

Duty to provide information about fitness to practise matters as they arise

17.—(1) Subject to paragraph 18, a supplier of appliances, and where the supplier of appliances is a body corporate every director of the supplier of appliances, shall, within 7 days of its occurrence, inform the Primary Care Trust in writing if he—

- (a) is convicted of any criminal offence in the United Kingdom;
- (b) is bound over following a criminal conviction in the United Kingdom;
- (c) accepts a police caution in the United Kingdom;

(a) 1997 c.50.

- (d) has, in summary proceedings in Scotland in respect of an offence, been the subject of an order discharging him absolutely (without proceeding to conviction);
- (e) has accepted and agreed to pay either a procurator fiscal fine under section 302 of the Criminal Procedure (Scotland) Act 1995 or a penalty under section 115A of the Social Security Administration Act 1992;
- (f) is convicted elsewhere of an offence, or what would constitute a criminal offence if committed in England and Wales;
- (g) is charged in the United Kingdom with a criminal offence, or is charged elsewhere with an offence which, if committed in England and Wales, would constitute a criminal offence;
- (h) is notified by any licensing, regulatory or other body of the outcome of any investigation into his professional conduct, and there is a finding against him;
- (i) becomes the subject of any investigation into his professional conduct by any licensing, regulatory or other body;
- (j) becomes subject to an investigation into his professional conduct in respect of any current or previous employment, or is notified of the outcome of any such investigation and any finding against him;
- (k) becomes the subject of any investigation by the National Health Service Counter Fraud and Security Management Service in relation to fraud;
- (l) becomes the subject of any investigation by another Primary Care Trust or equivalent body, which might lead to his removal from any list or equivalent list; or
- (m) is removed, contingently removed or suspended from, refused admission to, or conditionally included in, any list, or equivalent list, on fitness to practise grounds,

and if so, he shall give details of any investigation or proceedings which were or are to be brought, including the nature of the investigation or proceedings, where and approximately when that investigation or those proceedings took place or are to take place, and any outcome.

(2) Subject to paragraph 18, if a person to whom paragraph (1) applies is, or was at the time of the originating events, a director of a body corporate, he shall in addition inform the Primary Care Trust within 7 days if any such body corporate—

- (a) is convicted of any criminal offence in the United Kingdom;
- (b) is convicted elsewhere of an offence, or what would constitute a criminal offence if committed in England and Wales;
- (c) is charged in the United Kingdom with a criminal offence, or is charged elsewhere with an offence which, if committed in England and Wales, would constitute a criminal offence;
- (d) is notified by any licensing, regulatory or other body of the outcome of any investigation into its provision of professional services, and there is a finding against the body corporate;
- (e) becomes the subject of any investigation into its provision of professional services by any licensing, regulatory or other body;
- (f) becomes the subject of any investigation by the National Health Service Counter Fraud and Security Management Service in relation to any fraud or is notified of the outcome of such an investigation where it is adverse;
- (g) becomes the subject of any investigation by another Primary Care Trust or equivalent body, which might lead to its removal from any list or equivalent list; or
- (h) is removed, contingently removed or suspended from, refused admission to, or conditionally included in any list, or equivalent list, on fitness to practise grounds,

and if so, he shall give the name and registered office of the body corporate and details of any investigation or proceedings which were or are to be brought, including the nature of the investigation or proceedings, where and approximately when that investigation or those proceedings took place or are to take place, and any outcome.

(3) A person to whom sub-paragraph (1) or (2) applies shall consent to a request being made by the Primary Care Trust to any employer or former employer or licensing or regulatory body in the United Kingdom or elsewhere, for information relating to a current investigation, or an investigation where the outcome was adverse.

Home Primary Care Trust of bodies corporate

18. Where a supplier of appliances is a body corporate with a registered office in England, the information to be provided under paragraphs 16 and 17 may be provided only to the Primary Care Trust in which that registered office is located, if the supplier of appliances also provides that Primary Care Trust with details of all the other Primary Care Trusts in whose pharmaceutical lists it is included, and in these circumstances that Primary Care Trust shall pass the information on to any other Primary Care Trust—

- (a) in whose pharmaceutical list the supplier of appliances is included; or
- (b) to whom the supplier of appliances makes an application to be included in its pharmaceutical list,

that requests it.

Complaints

19. A supplier of appliances shall have in place arrangements for the handling and consideration of complaints about any matter connected with his provision of pharmaceutical services which are essentially the same as those set out in Part II of the National Health Service (Complaints) Regulations 2004(a).

Directed Services

20.—(1) A supplier of appliances with whom a Primary Care Trust makes an arrangement for the provision of any directed services shall comply with the terms and conditions of the arrangement.

(2) Where, by virtue of regulation 13(3)(b), it is a condition of a supplier of appliances' inclusion in a pharmaceutical list that he provides specified directed services where requested to do so by the Primary Care Trust, that supplier of appliances shall comply with any such request within such period as the Primary Care Trust may specify.

Information to be supplied

21.—(1) A supplier of appliances shall give notice to the Primary Care Trust within 28 days (or if this is impracticable, as soon as practicable thereafter) of—

- (a) any occurrence requiring a change in the information recorded about him in the pharmaceutical list which he has not otherwise notified to him in accordance with these Regulations;
- (b) in the case of a supplier of appliances who is an individual, any change of his private address;
- (c) in the case of a supplier of appliances that is a body corporate, any change to the address of his registered office; and
- (d) any occurrence requiring his addition to or removal from the ETP list or a change in the information recorded about him in that list.

(2) A supplier of appliances shall give the Primary Care Trust, if it so requests, the name of any registered pharmacist employed by him who is responsible for dispensing a particular prescription.

(a) S.I. 2004/1768; *see also* regulation 4 of those Regulations which imposes a requirement on Primary Care Trusts to ensure that suppliers of appliances have such arrangements in place.

(3) Subject to sub-paragraph (7), a supplier of appliances that is a body corporate shall (if he is on a pharmaceutical list on 1st April 2005, by 3rd October 2005) supply to his Primary Care Trust in writing the name and address of each of his directors, and any changes to the names and addresses of each of its directors.

(4) Subject to sub-paragraph (7), if a supplier of appliances or the director of a supplier of appliances that is a body corporate is himself on, or is a director of a body corporate which is on, another NHS performers or providers list (that is, on a list other than the pharmaceutical list referred to in sub-paragraph (1)), that person shall supply in writing to the Primary Care Trust—

- (a) if he is a director of a body corporate, the name and registered office of the body corporate on the other NHS performers or providers list; and
- (b) particulars of the other NHS performers or providers list.

(5) Subject to sub-paragraph (7), if a supplier of appliances or the director of a supplier of appliances that is a body corporate has himself in the five years prior to 1st April 2005 been on, or has in the five years prior to 1st April 2005 been the director of a body corporate which was when he was a director on, another NHS performers or providers list (that is, on a list other than the pharmaceutical list referred to in sub-paragraph (1)), that person shall supply in writing to the Primary Care Trust—

- (a) the name and registered office of the body corporate on the other NHS performers or providers list; and
- (b) particulars of the NHS performers or providers list,

unless that information has already been supplied pursuant to sub-paragraph (4).

(6) Subject to sub-paragraph (7), if a supplier of appliances, or the director of a supplier of appliances that is a body corporate, shall inform the Primary Care Trust—

- (a) if he, or a body corporate of which he is a director, applies to be included in any of another Primary Care Trust's NHS performers or providers lists, and of the outcome of any such application; and
- (b) if he becomes a director of a body corporate which is on any of another Primary Care Trust's NHS performers or providers lists, or which applies to be included in such a list, and the outcome of any such application.

(7) Where a supplier of appliances is a body corporate with a registered office in England, the information to be provided under sub-paragraphs (3) to (6) may be provided only to the Primary Care Trust in which that registered office is located, if the supplier of appliances also provides that Primary Care Trust with details of all the other Primary Care Trusts in whose pharmaceutical lists it is included, and in these circumstances that Primary Care Trust shall pass the information on to any other Primary Care Trust—

- (a) in whose pharmaceutical list the supplier of appliances is included; or
- (b) to whom the supplier of appliances makes an application to be included in its pharmaceutical list,

that requests it.

(8) In this paragraph, "NHS performers or providers list" means—

- (a) a pharmaceutical list; or
- (b) any other list.

Withdrawal from pharmaceutical lists

22. Where a supplier of appliances intends to withdraw from the pharmaceutical list in respect of particular premises, he shall notify the Primary Care Trust of this—

- (a) at least three months in advance of that date; or
- (b) in the case of a supplier of appliances in respect of whom a condition is imposed by virtue of regulation 13(2)(a) as regards those premises, at least six months in advance of that date,

unless it is impracticable for him to do so in which case he shall notify the Primary Care Trust as soon as it is practicable for him to do so.

Charges for appliances

23. Subject to regulations made under section 77 of the Act, all appliances provided under these terms of service shall be provided free of charge.

Inspections and access to information

24.—(1) A supplier of appliances shall allow persons authorised in writing by the Primary Care Trust to enter and inspect any premises he uses for the provision of pharmaceutical services at any reasonable time, for the purposes of—

- (a) ascertaining whether or not the supplier of appliances is complying with the requirements of this Schedule;
- (b) auditing, monitoring and analysing—
 - (i) the provision made by the supplier of appliances, in the course of providing pharmaceutical services, for patient care and treatment, and
 - (ii) the management by the supplier of appliances of the pharmaceutical services he provides,

where the conditions in sub-paragraph (2) are satisfied.

(2) The conditions are that—

- (a) reasonable notice of the intended entry has been given;
- (b) the Local Pharmaceutical Committee for the area where the premises are situated have been invited to be present at the inspection, where this is requested by the supplier of appliances;
- (c) the person authorised in writing carries written evidence of his authorisation, which he produces on request; and
- (d) he does not enter any part of the premises used solely as residential accommodation without the consent of the resident.

(3) A supplier of appliances shall, at the request of the Primary Care Trust or of a person authorised in writing mentioned in sub-paragraph (1), allow it or him access to any information which it or he reasonably requires—

- (a) for the purposes mentioned in sub-paragraph (1); or
- (b) in the case of the Primary Care Trust, in connection with its functions that relate to pharmaceutical services.

SCHEDULE 4

Regulations 5(1) and (2), 10(3) and (4), 39(2), 40(2) and 54(3) and (7)

Part 1

INFORMATION TO BE INCLUDED IN AN APPLICATION FOR INCLUSION IN A PHARMACEUTICAL LIST OR INCLUSION IN A LIST IN RESPECT OF DIFFERENT SERVICES OR PREMISES

1. APPLICATION

Name of the Primary Care Trust to which the application is made.

The type of consent applied for (preliminary or full).

The type of application (for example, application for change of premises, change of ownership etc.).

2. DETAILS OF APPLICANT

Name and address of applicant.

The applicant's Royal Pharmaceutical Society of Great Britain registration number.

Where the applicant is a corporate body, name and registration number of superintendent (where known).

Where the applicant is a temporary chemist, the name of the suspended chemist.

3. DETAILS OF PREMISES AND OPENING HOURS

Name and address of premises or where seeking preliminary consent, relevant location of premises.

Whether the applicant is currently in possession of the premises.

Proposed hours during which the applicant will be obliged to remain open by virtue of paragraph 22(1) of Schedule 1 or paragraph 10(1) of Schedule 3, and days on which and times at which pharmaceutical services will be provided if the application is granted.

Proposed opening hours, if any, during which the applicant proposes to open in addition to those during which he is obliged to remain open and days on which and times at which pharmaceutical services will be provided if the application is granted in relation to those additional hours.

4. PHARMACEUTICAL SERVICES TO BE PROVIDED

Confirmation that all essential services will be provided.

If directed services are to be provided—

- (a) details of the services to be provided;
- (b) confirmation that the applicant is accredited to provide such directed services where accreditation is a requirement for the provision of those services;
- (c) confirmation that the premises are accredited where accreditation is a requirement for the provision of those services; and
- (d) floor plan showing consultation area where the applicant proposes to offer directed services (where available and relevant).

5. NECESSARY OR DESIRABLE TEST

Where regulation 12 applies, reasons why the applicant considers the granting of the application is necessary or desirable in order to secure the adequate provision of pharmaceutical services in that neighbourhood.

Where an applicant does not wish to rely on an exemption under regulation 13, a statement that the applicant does not want the exemptions to apply.

Where regulation 13 applies and the applicant does seek to rely on an exemption, which exemption is applicable and—

- (a) where regulation 13(1)(a) applies—
 - (i) the name of the approved retail area,
 - (ii) confirmation that the retail area is approved by the Secretary of State under regulation 15(1), and
 - (iii) details of the directed services the applicant will undertake;
- (b) where regulation 13(1)(b) applies—
 - (i) details of how the pharmacy will be staffed during its opening hours, and
 - (ii) details of the directed services the applicant will undertake;
- (c) where regulation 13(1)(c) applies—

- (i) the names of the persons carrying on business as a consortium,
 - (ii) an outline of its management and equity structure,
 - (iii) the articles of association of the consortium,
 - (iv) confirmation that the one-stop primary care centre is part of the Primary Care Trust's strategic service development plan or equivalent plan and was included in that plan for the first time on or after 1st April 2005,
 - (v) the number of patients on the patient list of the provider of primary medical services and the name and address of that provider,
 - (vi) details of the health and social services to be provided from the one-stop primary care centre, and
 - (vii) details of the directed services the applicant will undertake; or
- (d) where regulation 13(1)(d) applies, details of how the applicant will provide the essential services.

6. APPLICATIONS MADE UNDER REGULATION 5(1)(b)(ii) OR 5(1)(c)

Where the application is made under regulation 5(1)(c), name of the Primary Care Trust where the existing premises are located and the consent required by regulation 7(1)(b).

Reasons for the relocation.

Where the application is in relation to a minor relocation, information as to why the relocation is minor and the distance of the new premises from the old premises by the nearest practicable route by foot where this is less than 500 metres.

Whether the provision of services will be continuous or interrupted, together with the reasons for any interruption.

7. APPLICATIONS MADE UNDER REGULATION 5(1)(b)(iii)

Details of additional services the applicant proposes to provide.

If directed services are to be provided—

- (a) details of the services to be provided;
- (b) confirmation that the applicant is accredited to provide such directed services where accreditation is a requirement for the provision of those services;
- (c) confirmation that the premises are accredited where accreditation is a requirement for the provision of those services; and
- (d) floor plan showing consultation area where the applicant proposes to offer directed services (where available and relevant).

8. APPLICATIONS MADE IN ACCORDANCE WITH REGULATION 8

Name of previous owner.

Whether the provision of services will be continuous or interrupted, together with the reasons for any interruption.

Whether the same services will be provided.

Part 2

NOTIFICATION OF COMMENCEMENT DATE

For Primary Care Trust use only – to be sent with the approval letter (Primary Care Trust can pre-populate this area when the full application has been granted)

APPLICATION RELATED TO PREMISES AT:

.....
.....
.....
.....

NAME OF PHARMACIST IN CHARGE AT PREMISES:

.....

SERVICES ENTITLED TO PROVIDE ARE:

.....
.....
.....
.....

APPLICATION GRANTED ON: DATE

APPLICANT

I/We intend to commence provision of the above services at the above premises on:

.....DATE

REGISTERED WITH Royal Pharmaceutical Society of Great Britain Yes No

REFERENCE

NO:.....

SIGNATURE.....DATE.....

Part 3

INFORMATION AND UNDERTAKINGS TO BE GIVEN BY AN APPLICANT IN CONNECTION WITH AN APPLICATION FOR INCLUSION (OR TEMPORARY INCLUSION) IN A PHARMACEUTICAL LIST

1. An applicant (other than an applicant which is a body corporate) shall provide the following information—
 - (a) his full name;
 - (b) his sex;
 - (c) his date of birth;
 - (d) his private address and telephone number;
 - (e) a declaration that he is a registered pharmacist; and
 - (f) his professional registration number and date of first registration in the register.
2. An applicant which is a body corporate shall provide the following information—
 - (a) its full name;
 - (b) its company registration number;
 - (c) its registered office and telephone number relating to that office;
 - (d) a declaration that it is a person who is or who will be lawfully conducting a retail pharmacy business in accordance with section 69 of the Medicines Act 1968;
 - (e) its registration number in the Register of Premises maintained by the Royal Pharmaceutical Society of Great Britain;
 - (f) details of any Primary Care Trust list or equivalent list from which it has been removed or contingently removed, or to which it has been refused admission or in which he has been conditionally included, on fitness to practise grounds, with an explanation as to why.
3. An applicant shall provide the following undertakings—
 - (a) an undertaking to notify the Primary Care Trust within 7 days of any material changes to the information provided in the application until the application is finally determined; and
 - (b) an undertaking to notify the Primary Care Trust if he is included, or applies to be included, in any other list or equivalent list held by a Primary Care Trust or equivalent body.
4. An applicant shall supply in writing information as to whether he, or where the applicant is a body corporate, any of its directors or its superintendents—
 - (a) has any criminal convictions in the United Kingdom;
 - (b) has been bound over following a criminal conviction in the United Kingdom;
 - (c) has accepted a police caution in the United Kingdom;
 - (d) has, in summary proceedings in Scotland in respect of an offence, been the subject of an order discharging him absolutely (without proceeding to conviction);
 - (e) has accepted a conditional offer under section 302 of the Criminal Procedure (Scotland) Act 1995 (fixed penalty: conditional offer by procurator fiscal) or agreed to pay a penalty under section 115A of the Social Security Administration Act 1992 (penalty as alternative to prosecution);
 - (f) has been convicted elsewhere of an offence, or what would constitute a criminal offence if committed in England and Wales;
 - (g) is currently the subject of any proceedings which might lead to such a conviction, which have not yet been notified to the Primary Care Trust;
 - (h) has been subject to any investigation into his professional conduct by any licensing, regulatory or other body, where the outcome was adverse;

- (i) is currently subject to any investigation into his professional conduct by any licensing, regulatory or other body;
- (j) is, or has been where the outcome was adverse, the subject of any investigation into his professional conduct in respect of any current or previous employment;
- (k) is the subject of any investigation by another Primary Care Trust or equivalent body, which might lead to his removal from any list or equivalent list;
- (l) is to his knowledge, or has been where the outcome was adverse, the subject of any investigation by the National Health Service Counter Fraud and Security Management Service in relation to fraud;
- (m) has been removed or contingently removed from, refused admission to, or conditionally included in, any list or equivalent list kept by another Primary Care Trust or equivalent body, or has been or is currently suspended from such a list, on fitness to practise grounds, and if so, why and the name of that Primary Care Trust or equivalent body; or
- (n) is, or ever has been, subject to a national disqualification,

and, if so, the applicant shall give details including approximate dates, or where any investigation or proceedings were or are to be brought, the nature of that investigation or proceedings, and any outcome.

5. If the applicant (and where the applicant is a body corporate, any director or superintendent of the applicant) is, has in the preceding six months been, or was at the time of the originating events, a director or superintendent of a body corporate, he shall in addition supply information in writing to the Primary Care Trust as to whether the body corporate—

- (a) has any criminal convictions in the United Kingdom;
- (b) has been convicted elsewhere of an offence, or what would constitute a criminal offence if committed in England and Wales;
- (c) is currently the subject of any proceedings which might lead to such a conviction, which have not yet been notified to the Primary Care Trust;
- (d) has been subject to any investigation into its provision of professional services by any licensing, regulatory or other body, where the outcome was adverse;
- (e) is currently subject to any investigation into its provision of professional services by any licensing, regulatory or other body;
- (f) is the subject of any investigation by another Primary Care Trust or equivalent body, which might lead to its removal from any list or equivalent list;
- (g) is, or has been where the outcome was adverse, the subject of any investigation by the National Health Service Counter Fraud and Security Management Service in relation to fraud;
- (h) has been removed or contingently removed from, refused admission to, or conditionally included in, any list or equivalent list, or has been or is currently suspended from such a list, on fitness to practise grounds; or
- (i) is, or ever has been, subject to a national disqualification,

and if so, the applicant shall give the name and address of the registered office of the body corporate and details, including approximate dates, of where any investigation or proceedings were or are to be brought, the nature of that investigation or proceedings, and any outcome.

6. Where the applicant (or where the applicant is a body corporate, any director or superintendent of the applicant) is a pharmacist, the applicant shall supply details of his pharmaceutical qualifications (including where obtained) and chronological details of his professional experience (including starting and finishing dates of each appointment), with an explanation of any gaps between appointments and of why he was dismissed from any post.

7. Where the applicant (or where the applicant is a body corporate, any director or superintendent of the applicant) is a pharmacist, the applicant shall supply names and addresses of

two referees who are willing to provide references in respect of two recent posts (which may include any current post) as a pharmacist which lasted at least three months without a significant break, or where this is not possible, a full explanation and alternative referees.

8. Where the applicant is a body corporate, the name and address of each director and superintendent of the body corporate shall be supplied.

9. The applicant shall supply the name of any Primary Care Trust (or equivalent body) in whose pharmaceutical list the applicant, and where the applicant is a body corporate, any director or superintendent of the applicant, is included, and particulars of any outstanding application (including deferred applications) for inclusion in, or preliminary consent to be included in, any pharmaceutical list of a Primary Care Trust (or equivalent body) with the name of the Trust (or body) in question.

10. If the applicant is the director or superintendent of a body corporate that is included in any of a Primary Care Trust's lists, or equivalent lists, or which has an outstanding application (including a deferred application) for inclusion in any of a Primary Care Trust's lists or equivalent lists, the applicant shall supply the name of the Primary Care Trust or equivalent body in question, and the name and registered office of any such body corporate.

11. If, in the case of any application, the Primary Care Trust finds that the information, references or documentation supplied by the applicant are not sufficient for it to determine his application, it shall seek from him such further information, references or documentation as it may reasonably require in order to make a decision, and he shall supply the material so sought to the Primary Care Trust.

12. The applicant shall give a written undertaking to notify the Primary Care Trust within 7 days of any material changes to the information provided in his application until such time as—

- (a) his name is entered on the pharmaceutical list;
- (b) the period specified in regulation 39(2) for him to notify the Primary Care Trust that he will commence the provision of the services in respect of which the application was made has expired;
- (c) he withdraws the application;
- (d) in the case of an applicant who has been granted preliminary consent under regulation 40, the period during which the preliminary consent has effect under regulation 40(5) has expired; or
- (e) the period for appealing against a Primary Care Trust's decision to refuse an application has expired and no appeal has been lodged, or an application has been refused on appeal either by the Secretary of State or the FHSAA.

SCHEDULE 5

Regulation 75(1)

MINOR AND CONSEQUENTIAL AMENDMENTS

The National Health Service (General Medical Services Contracts) (Personal Medical Services Agreements) and (Pharmaceutical Services) (Amendment) Regulations 2005

1. In the National Health Service (General Medical Services Contracts) (Personal Medical Services Agreements) and (Pharmaceutical Services) (Amendment) Regulations 2005(a), omit regulation 4 (amendment of the Pharmaceutical Services Regulations).

(a) S.I. 2005/28.

The Health Act 1999 (Consequential Amendments) (Nursing and Midwifery) Order 2004

2. In the Schedule to the Health Act 1999 (Consequential Amendments) (Nursing and Midwifery) Order 2004(a) (consequential amendments to primary and secondary legislation), omit paragraph 45 (National Health Service (Pharmaceutical Services) Regulations 1992).

The Health and Social Care (Community Health and Standards) Act 2003 (Supplementary and Consequential Provision) (NHS Foundation Trusts) Order 2004

3. In Schedule 1 to the Health and Social Care (Community Health and Standards) Act 2003 (Supplementary and Consequential Provision) (NHS Foundation Trusts) Order 2004(b) (amendments supplementary and consequential on Part 1 of the Health and Social Care (Community Health and Standards) Act 2003), omit paragraph 11 (National Health Service (Pharmaceutical Services) Regulations 1992).

The Nurses and Midwives (Parts of and Entries in the Register) Order of Council 2004

4. In article 1 of the Nurses and Midwives (Parts of and Entries in the Register) Order of Council 2004(c) (citation, commencement and interpretation) in the definition of “Drug Tariff”, for sub-paragraph (a), substitute—

“(a) in England, the Drug Tariff published under regulation 56 (standards of, and payments for, drugs and appliances) of the National Health Service (Pharmaceutical Services) Regulations 2005;

(aa) in Wales, the Drug Tariff published under regulation 18 (standards of, and payments for, drugs and appliances) of the National Health Service (Pharmaceutical Services) Regulations 1992”.

The National Health Service (General Medical Services etc) (Patients’ Forums) Amendment Regulations 2003

5. In the National Health Service (General Medical Services etc) (Patients’ Forums) Amendment Regulations 2003(d), omit regulation 5 (amendment of the Pharmaceutical Regulations).

The National Health Service (Pharmaceutical Services) (General Medical Services) and (Charges for Drugs and Appliances) Amendment Regulations 2003

6. In the National Health Service (Pharmaceutical Services) (General Medical Services) and (Charges for Drugs and Appliances) Amendment Regulations 2003(e), omit Part 1 (amendment of the National Health Service (Pharmaceutical Services) Regulations 1992).

The National Health Service (Amendments Relating to Prescribing by Nurses and Pharmacists etc) (England) Regulations 2003

7. In the National Health Service (Amendments Relating to Prescribing by Nurses and Pharmacists etc) (England) Regulations 2003(f), omit regulation 2 (amendment of the National Health Service (Pharmaceutical Services) Regulations 1992).

The National Health Service (Local Pharmaceutical Services Etc) Regulations 2002

8. In the National Health Service (Local Pharmaceutical Services Etc) Regulations 2002(a), omit—

-
- (a) S.I. 2004/1771.
(b) S.I. 2004/696.
(c) S.I. 2004/1765.
(d) S.I. 2003/2863.
(e) S.I. 2003/1084.
(f) S.I. 2003/699.

- (a) Part 1 (amendment of the National Health Service (Pharmaceutical Services) Regulations 1992); and
- (b) the Schedule (provisions of the National Health Service (Pharmaceutical Services) Regulations 1992 specified for the purposes of regulation 15).

The National Health Service Reform and Health Care Professions Act 2002 (Supplementary, Consequential etc Provisions) Regulations 2002

9.—(1) The National Health Service Reform and Health Care Professions Act 2002 (Supplementary, Consequential etc Provisions) Regulations 2002(b) shall be amended in accordance with this paragraph.

(2) In Schedule 1 (amendments consequential on Part 1 of the National Health Service Reform and Health Care Professions Act 2002), omit paragraph 57 (National Health Service (Pharmaceutical Services) Regulations 1992).

(3) In each of the tables in—

- (a) Schedule 5 (enactments where after “Health Authority”, “Health Authorities” or “Health Authority’s” there is inserted “or Primary Care Trust”, “or Primary Care Trusts” or “or Primary Care Trust’s”);
- (b) Schedule 7 (enactments where for “Health Authority”, “District Health Authority”, “Health Authorities” or “Health Authority’s” there is substituted “Primary Care Trust”, “Primary Care Trusts” or “Primary Care Trust’s”); and
- (c) Schedule 10 (enactments where for “Family Health Services Authority”, “FHSA”, “Family Practitioner Committee” or “FHSA’s” there is substituted “Health Authority or Primary Care Trust” or “Health Authority’s or Primary Care Trust’s”),

omit the entry in column 1 relating to the National Health Service (Pharmaceutical Services) Regulations 1992, together with the corresponding entry in column 2 of each of those tables.

The National Health Service (Local Pharmaceutical Services and Pharmaceutical Services) (No. 2) Regulations 2002

10.—(1) The National Health Service (Local Pharmaceutical Services and Pharmaceutical Services) (No. 2) Regulations 2002(c) shall be amended in accordance with this paragraph.

(2) In regulation 1(3) (citation, commencement, extent and interpretation), in the definition of “the principal Regulations” for the words “National Health Service (Pharmaceutical Services) Regulations 1992”, substitute “National Health Service (Pharmaceutical Services) Regulations 2005”.

(3) In regulation 4(1) (right of return to pharmaceutical lists)(d), for the words “regulation 8A” substitute “regulation 10”.

(4) Omit regulation 5 (amendment of the principal Regulations).

The National Health Service (Local Pharmaceutical Services and Pharmaceutical Services) Regulations 2002

11.—(1) The National Health Service (Local Pharmaceutical Services and Pharmaceutical Services) Regulations 2002(e) shall be amended in accordance with this paragraph.

(2) In regulation 1(3) (citation, commencement, extent and interpretation), in the definition of “the principal Regulations”, for the words “National Health Service (Pharmaceutical Services) Regulations 1992” substitute “National Health Service (Pharmaceutical Services) Regulations 2005”.

(a) S.I. 2002/2861.

(b) S.I. 2002/2469.

(c) S.I. 2002/2016.

(d) Regulation 4(1) was previously amended by S.I. 2002/2469.

(e) S.I. 2002/888.

(3) In regulation 3(7)(d) (designation of priority neighbourhoods or premises), for the words “regulation 21B” substitute “regulation 68”.

(4) Omit regulation 10 (amendment of the principal Regulations).

The National Health Service (Pharmaceutical Services) and (Misuse of Drugs) (Electronic Communications) Order 2001

12. In the National Health Service (Pharmaceutical Services) and (Misuse of Drugs) (Electronic Communications) Order 2001(a), omit regulations 2 to 5 (amendment of the National Health Service (Pharmaceutical Services) Regulations 1992).

The National Health Service (Charges for Drugs and Appliances) Regulations 2000

13. In regulation 2 of the National Health Service (Charges for Drugs and Appliances) Regulations 2000(b) (interpretation), in the definition of “Drug Tariff”, for the words “regulation 18 of the National Health Service (Pharmaceutical Services) Regulations 1992” substitute “regulation 56 of the National Health Service (Pharmaceutical Services) Regulations 2005”.

The National Health Service (Payments by Local Authorities to NHS Bodies) (Prescribed Functions) Regulations 2000

14. In regulation 2(2)(d) of the National Health Service (Payments by Local Authorities to NHS Bodies) (Prescribed Functions) Regulations 2000(c) (prescribed functions of relevant NHS bodies), for the words “regulation 18(1) of the National Health Service (Pharmaceutical Services) Regulations 1992” substitute “regulation 56(1) of the National Health Service (Pharmaceutical Services) Regulations 2005”.

The National Health Service (Pilot Schemes for Personal Dental Services: Miscellaneous Provisions and Consequential Amendments) Regulations 1998

15. In the National Health Service (Pilot Schemes for Personal Dental Services: Miscellaneous Provisions and Consequential Amendments) Regulations 1998(d), omit regulation 7 (amendment of the National Health Service (Pharmaceutical Services) Regulations 1992).

The National Health Service (Indicative Amounts) Regulations 1997

16. In regulation 1(2) of the National Health Service (Indicative Amounts) Regulations 1997(e) in the definition of “the Drug Tariff”, for the words “regulation 18 of the National Health Service (Pharmaceutical Services) Regulations 1992” substitute “regulation 56 of the National Health Service (Pharmaceutical Services) Regulations 2005”.

The National Health Service (Service Committees and Tribunal) Regulations 1992

17. In regulation 2 of the National Health Service (Service Committees and Tribunal) Regulations 1992(f) (interpretation)—

- (a) in paragraph (1), in the definition of “Pharmaceutical Regulations”, for the words “National Health Service (Pharmaceutical Services) Regulations 1992” substitute “National Health Service (Pharmaceutical Services) Regulations 2005”; and
- (b) in paragraph (4)(c)(a), for the words “paragraphs 10A and 10B of Schedule 2 to the National Health Service (Pharmaceutical Services) Regulations 1992” substitute

(a) S.I. 2001/2888.

(b) S.I. 2000/620. The definition of “Drug Tariff” was inserted into regulation 2 by S.I. 2003/699.

(c) S.I. 2000/618.

(d) S.I. 1998/2224.

(e) S.I. 1997/980.

(f) S.I. 1992/664.

“paragraph 32 of Schedule 1 to, or paragraph 19 of Schedule 3 to, the Pharmaceutical Regulations.”

The National Health Service (General Dental Services) Regulations 1992

18. In regulation 2(1) of the National Health Service (General Dental Services) Regulations 1992**(b)** (interpretation) in the definition of “Drug Tariff”, for the words “regulation 18 of the National Health Service (Pharmaceutical Services) Regulations 1992” substitute “regulation 56 of the National Health Service (Pharmaceutical Services) Regulations 2005”.

SCHEDULE 6

Regulation 75(2)

REVOCATIONS

The Health Act 1999 (Consequential Amendments) (Nursing and Midwifery) Order 2004	S.I. 2004/1771	Paragraph 45 of the Schedule
The National Health Service (Pharmaceutical Services) (Amendment) Regulations 2004	S.I. 2004/922	The whole Regulations
The Health and Social Care (Community Health and Standards) Act 2003 (Supplementary and Consequential Provisions) (NHS Foundation Trusts) Order 2004	S.I. 2004/696	Paragraph 11 of Schedule 1
The National Health Service (General Medical Services etc) (Patients’ Forums) Amendment Regulations 2003	S.I. 2003/2863	Regulation 5
The National Health Service (Pharmaceutical Services) (General Medical Services) and (Charges for Drugs and Appliances) Amendment Regulations 2003	S.I. 2003/1084	Part 1 of the Regulations
The National Health Service (Amendments Relating to Prescribing by Nurses and Pharmacists etc) (England) Regulations 2003	S.I. 2003/699	Regulation 2
The National Health Service (Local Pharmaceutical Services Etc) Regulations 2002	S.I. 2002/2861	Part 1 of the Regulations and the Schedule
The National Health Service Reform and Health Care Professions Act 2002 (Supplementary,	S.I. 2002/2469	Paragraph 57 of Schedule 1

(a) Paragraph (4)(c) was inserted by S.I. 1996/703 and was, in relation to England, amended by S.I. 2004/865.

(b) S.I. 1992/661.

Consequential etc Provisions) Regulations 2002		
The National Health Service (Pharmaceutical Services) and (General Medical Services) (No. 2) Amendment Regulations 2002	S.I. 2002/551	The whole Regulations
The National Health Service (Pharmaceutical Services) Amendment (No. 2) Regulations 2000	S.I. 2000/593	The whole Regulations
The National Health Service (Pharmaceutical Services) Amendment Regulations 2000	S.I. 2000/121	The whole Regulations
The National Health Service (Pharmaceutical Services) Amendment (No. 2) Regulations 1999	S.I. 1999/2563	The whole Regulations
The National Health Service (Pharmaceutical Services) Amendment Regulations 1999	S.I. 1999/696	The whole Regulations
The National Health Service (Pharmaceutical Services) Amendment Regulations 1998	S.I. 1998/681	The whole Regulations
The National Health Service (Pharmaceutical Services) Amendment Regulations 1996	S.I. 1996/698	The whole Regulations
The National Health Service (Pharmaceutical Services) Amendment Regulations 1995	S.I. 1995/644	The whole Regulations
The National Health Service (Pharmaceutical Services and Charges for Drugs and Appliances) Amendment Regulations 1994	S.I. 1994/2402	The whole Regulations
The National Health Service (Pharmaceutical Services) Amendment Regulations 1993	S.I. 1993/2451	The whole Regulations
The National Health Service (Pharmaceutical Services) Regulations 1992	S.I. 1992/662	The whole Regulations

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations replace the National Health Service (Pharmaceutical Services) Regulations 1992 which govern the provision of pharmaceutical services under Part 2 of the National Health Service Act 1977.

Primary Care Trusts are required to keep lists of persons providing pharmaceutical services in their area (regulation 4) and provide for applications to be made for inclusion in a list and for amendment to a list (regulation 5 and Schedule 4).

Regulation 5(1) sets out the different types of applications. Relatively straightforward applications are dealt with under their own provisions (regulation 6 (minor relocations within a Primary Care Trust's area), regulation 7 (minor relocations between neighbouring Primary Care Trusts), regulation 8 (changes of ownership), regulation 9 (applications following suspension), regulation 10 (returning to the pharmaceutical list after providing local pharmaceutical services) and regulation 54 (the temporary provision of services during a period of suspension)). The grant or refusal of other applications (including applications to be included in the pharmaceutical list for the first time) are dealt with under regulations 11 and 13 to 21. The procedures for determining these applications are listed in regulation 22 and depend essentially on whether the application relates to a controlled locality (which is typically a rural area) or not.

Where the application does not concern premises in a controlled locality, it will be determined in accordance with the procedures set out in regulations 12(2) to (4), 22(4), and 23 to 30. Where the application does concern premises within a controlled locality, it will be determined in accordance with regulations 12(2) to (4), 22(4), 25, 26, 28, and 30 to 38.

Generally, applications will only be granted if the Primary Care Trust considers that it is necessary or desirable to do so in order to secure the adequate provision of pharmaceutical services in its area (regulation 12). However, in certain circumstances, applications will be granted without satisfying this requirement. These circumstances are:

- (a) where the premises are in an approved retail area, which is essentially a large out of town centre shopping development (regulation 13(1)(a) and 15),
- (b) where the premises will be open for at least 100 hours a week (regulation 13(1)(b)),
- (c) where the premises are in a new one-stop primary care centre where a number of primary health care services are provided from a discrete building or site (regulation 13(1)(c) and 16), and
- (d) where the pharmaceutical services are not provided at the premises, but are instead provided by the Internet or by mail order (regulation 13(1)(d)).

The Regulations allow the Primary Care Trust to consider the fitness to practise of applicants. The Primary Care Trust can refuse an application (regulation 19) or can impose conditions on the applicant's entry in the list (regulation 21).

Once included in a pharmaceutical list or a dispensing doctors list, a chemist or doctor must provide pharmaceutical services in accordance with the terms of service. The terms of service for pharmacists are set out in Schedule 1. All pharmacists must provide the essential services described in Part 2 of that Schedule. The terms of service for dispensing doctors are set out in Schedule 2, and those for appliance contractors are set out in Schedule 3.

Part 3 of the Regulations concern matters arising after the applicant has been included in the pharmaceutical list and is primarily concerned with fitness to practise issues. It provides for the review of conditions imposed on fitness to practise grounds (regulations 42 and 43), removal from the pharmaceutical list (regulations 44 to 49), suspension from the pharmaceutical list (regulations 50 and 54), review of fitness to practise decisions (regulations 51 and 52) and withdrawal from the pharmaceutical list (regulation 53). The right of appeal against decisions in relation to fitness to practise matters is to the Family Health Services Appeals Authority.

Part 4 of the Regulations make provision for the payment of chemists (regulations 56 to 59).

Part 5 of the Regulations make provision for doctors to provide pharmaceutical services to patients in limited circumstances (regulations 60 to 69).

Part 6 of the Regulations makes miscellaneous provision regarding publication of particulars (regulation 70), the keeping of a list of chemists who provide an electronic prescription service (regulation 71), choice of chemist by patients (regulation 72) and transitional provisions (regulations 73 and 74). Regulation 75(1) and Schedule 5 make amendments to other legislation consequential on these Regulations and regulation 75(2) and Schedule 6 revoke legislation consequential on these Regulations.