

## SCHEDULE 1

Regulation 3(a)

### 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<sup>(1)</sup> 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<sup>(2)</sup> 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.

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(1) S.I. 1992/664.

(2) S.I. 2003/2124. Regulation 3 has been amended by S.I. 2004/540, 696 and 865.

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## 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(3), other than a drug which is for the time being specified in Schedule 4 or 5 to the Misuse of Drugs Regulations 2001(4), 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

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(3) 1971 c. 38: see section 2(1)(a) of that Act, which defines “controlled drug” for the purposes of that Act.

(4) S.I. 2001/3998. Schedule 4 has been amended by S.I. 2003/1432.

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Misuse of Drugs Regulations 2001, signed by a repeatable prescriber and including the reference “SLS”,

- (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—

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- (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(5) 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—

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(5) 1985 c. 72.

- (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.

(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

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(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.

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(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;

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- (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—

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- (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—

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- (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—

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- (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.

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(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;

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- (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,

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- (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”(6),

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(6) This Code of Practice is available at [www.dh.gov.uk/publicationsandstatistics](http://www.dh.gov.uk/publicationsandstatistics).

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- (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<sup>(7)</sup> (fixed penalty: conditional offer by procurator fiscal) or agreed to pay a penalty under section 115A of the Social Security Administration Act 1992<sup>(8)</sup> (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;

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(7) 1995 c. 46.

(8) 1992 c. 5; section 115A was inserted by section 15 of the Social Security Administration (Fraud) Act 1997 (c. 47).

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(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

(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<sup>(9)</sup> (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**

**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;

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(9) 1997 c. 50.

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- (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<sup>(10)</sup>.

## **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.

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<sup>(10)</sup> *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.

(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) 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.

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(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<sup>(11)</sup> 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<sup>(12)</sup> 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.

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<sup>(11)</sup> S.I. 1992/664.

<sup>(12)</sup> S.I. 2003/2124. Regulation 3 has been amended by S.I. 2004/540, 696 and 865.

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### **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
  - (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(13), other than a drug which is for the time being specified in Schedule 4 or 5 to the Misuse of Drugs Regulations 2001(14), 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

(13) 1971 c. 38; see section 2(1)(a) of that Act, which defines “controlled drug” for the purposes of that Act.

(14) S.I. 2001/3998. Schedule 4 has been amended by S.I. 2003/1432.

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- 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
  - (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.

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### **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.

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### **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<sup>(15)</sup> 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
- (d) so much of regulation 3 of the Patients' Forums (Functions) Regulations 2003<sup>(16)</sup> 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

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<sup>(15)</sup> S.I. 1992/664.

<sup>(16)</sup> S.I. 2003/2124. Regulation 3 has been amended by S.I. 2004/540, 696 and 865.

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- (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.

### **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<sup>(17)</sup> 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
- (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.

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(17) 1985 c. 72.

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### **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

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- (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—

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(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,

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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.

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(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<sup>(18)</sup> (fixed penalty: conditional offer by procurator fiscal) or agreed to pay a penalty under section 115A of the Social Security Administration Act 1992<sup>(19)</sup> (penalty as alternative to prosecution);

<sup>(18)</sup> 1995 c. 46.

<sup>(19)</sup> 1992 c. 5; section 115A was inserted by section 15 of the Social Security Administration (Fraud) Act 1997 (c. 47).



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- (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
  - (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 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.

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(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<sup>(20)</sup> (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;
- (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—

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<sup>(20)</sup> 1997 c. 50.

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- (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<sup>(21)</sup>.

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(21) *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.

## **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.

(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—

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- (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.

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- (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

##### **APPLICATION**

1. 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.).

##### **DETAILS OF APPLICANT**

2. 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.

##### **DETAILS OF PREMISES AND OPENING HOURS**

3. 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.

#### **PHARMACEUTICAL SERVICES TO BE PROVIDED**

**4.** 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).

#### **NECESSARY OR DESIRABLE TEST**

**5.** 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,

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- (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.

**APPLICATIONS MADE UNDER REGULATION 5(1)(b)(ii) OR 5(1)(c)**

6. 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.

**APPLICATIONS MADE UNDER REGULATION 5(1)(b)(iii)**

7. 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).

**APPLICATIONS MADE IN ACCORDANCE WITH REGULATION 8**

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.



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## 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.....

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### 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;

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- (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.

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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(22), omit regulation 4 (amendment of the Pharmaceutical Services Regulations).

#### **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(23) (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(24) (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(25) (citation, commencement and interpretation) in the definition of “Drug Tariff”, for subparagraph (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(26), omit regulation 5 (amendment of the Pharmaceutical Regulations).

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(22) [S.I. 2005/28](#).  
(23) [S.I. 2004/1771](#).  
(24) [S.I. 2004/696](#).  
(25) [S.I. 2004/1765](#).  
(26) [S.I. 2003/2863](#).

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**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(27), 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(28), 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(29), omit—

- (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(30) 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.

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(27) S.I. 2003/1084.

(28) S.I. 2003/699.

(29) S.I. 2002/2861.

(30) S.I. 2002/2469.

### **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(31) 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)(32), 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(33) 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 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(34), 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(35) (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(36) (prescribed functions of relevant NHS

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(31) [S.I. 2002/2016](#).

(32) Regulation 4(1) was previously amended by [S.I. 2002/2469](#).

(33) [S.I. 2002/888](#).

(34) [S.I. 2001/2888](#).

(35) [S.I. 2000/620](#). The definition of “Drug Tariff” was inserted into regulation 2 by [S.I. 2003/699](#).

(36) [S.I. 2000/618](#).

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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<sup>(37)</sup>, 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<sup>(38)</sup> 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<sup>(39)</sup> (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)<sup>(40)</sup>, for the words “paragraphs 10A and 10B of Schedule 2 to the National Health Service (Pharmaceutical Services) Regulations 1992” substitute “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<sup>(41)</sup> (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

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The Health Act 1999 (Consequential Amendments) (Nursing and Midwifery) Order 2004	<a href="#">S.I. 2004/1771</a>	Paragraph 45 of the Schedule
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<sup>(37)</sup> [S.I. 1998/2224](#).

<sup>(38)</sup> [S.I. 1997/980](#).

<sup>(39)</sup> [S.I. 1992/664](#).

<sup>(40)</sup> Paragraph (4)(c) was inserted by [S.I. 1996/703](#) and was, in relation to England, amended by [S.I. 2004/865](#).

<sup>(41)</sup> [S.I. 1992/661](#).



The National Health Service (Pharmaceutical Services) (Amendment) Regulations 2004	<a href="#">S.I. 2004/922</a>	The whole Regulations
The Health and Social Care (Community Health and Standards) Act 2003 (Supplementary and Consequential Provisions) (NHS Foundation Trusts) Order 2004	<a href="#">S.I. 2004/696</a>	Paragraph 11 of Schedule 1
The National Health Service (General Medical Services etc) (Patients' Forums) Amendment Regulations 2003	<a href="#">S.I. 2003/2863</a>	Regulation 5
The National Health Service (Pharmaceutical Services) (General Medical Services) and (Charges for Drugs and Appliances) Amendment Regulations 2003	<a href="#">S.I. 2003/1084</a>	Part 1 of the Regulations
The National Health Service (Amendments Relating to Prescribing by Nurses and Pharmacists etc) (England) Regulations 2003	<a href="#">S.I. 2003/699</a>	Regulation 2
The National Health Service (Local Pharmaceutical Services Etc) Regulations 2002	<a href="#">S.I. 2002/2861</a>	Part 1 of the Regulations and the Schedule
The National Health Service Reform and Health Care Professions Act 2002 (Supplementary, Consequential etc Provisions) Regulations 2002	<a href="#">S.I. 2002/2469</a>	Paragraph 57 of Schedule 1
The National Health Service (Pharmaceutical Services) and (General Medical Services) (No. 2) Amendment Regulations 2002	<a href="#">S.I. 2002/551</a>	The whole Regulations
The National Health Service (Pharmaceutical Services) Amendment (No. 2) Regulations 2000	<a href="#">S.I. 2000/593</a>	The whole Regulations
The National Health Service (Pharmaceutical Services) Amendment Regulations 2000	<a href="#">S.I. 2000/121</a>	The whole Regulations

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The National Health Service (Pharmaceutical Services) Amendment (No. 2) Regulations 1999	<a href="#">S.I. 1999/2563</a>	The whole Regulations
The National Health Service (Pharmaceutical Services) Amendment Regulations 1999	<a href="#">S.I. 1999/696</a>	The whole Regulations
The National Health Service (Pharmaceutical Services) Amendment Regulations 1998	<a href="#">S.I. 1998/681</a>	The whole Regulations
The National Health Service (Pharmaceutical Services) Amendment Regulations 1996	<a href="#">S.I. 1996/698</a>	The whole Regulations
The National Health Service (Pharmaceutical Services) Amendment Regulations 1995	<a href="#">S.I. 1995/644</a>	The whole Regulations
The National Health Service (Pharmaceutical Services and Charges for Drugs and Appliances) Amendment Regulations 1994	<a href="#">S.I. 1994/2402</a>	The whole Regulations
The National Health Service (Pharmaceutical Services) Amendment Regulations 1993	<a href="#">S.I. 1993/2451</a>	The whole Regulations
The National Health Service (Pharmaceutical Services) Regulations 1992	<a href="#">S.I. 1992/662</a>	The whole Regulations

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