INTERIM GUIDANCE

SAFER MANAGEMENT OF CONTROLLED DRUGS (CDs):

2. PRIVATE CD PRESCRIPTIONS AND OTHER CHANGES TO THE PRESCRIBING AND DISPENSING OF CONTROLLED DRUGS (CDs).

Guidance for Implementation

Department Of Health
Gateway Reference: 6212

March 2006 (Interim Guidance version 1)

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Interim Department of Health Guidance intended for prescriptions issued by doctors and other healthcare professionals who have prescribing or dispensing responsibilities. This particular guidance applies to England only.

Action Summary

1 This document sets out the action required to implement a series of changes to the way controlled drugs (CDs) for human use are prescribed and dispensed and the monitoring of this activity. The main changes are:

- Introduction of **special forms for any private prescription** (FP10PCD) of schedule 2 & 3 controlled drugs (CDs) dispensed by a community pharmacist – affects private prescribers, dispensing doctors, community pharmacists both with and without NHS dispensing contracts, PCTs and patients;
- Modified arrangements for dispensing of prescriptions for schedule 2 & 3 controlled drugs (CDs), including a **new requirement for patients or other persons collecting medicines on their behalf to sign for them** (this applies to both NHS and private prescriptions) – affects dispensing doctors, community pharmacists and patients;
- Prescriptions for schedule 2, 3 & 4 controlled drugs (CDs) will be valid for 28 days (this applies to all prescriptions and is a reduction from the current 91 days) – affects prescribers, dispensing doctors, pharmacists and patients;
- Strong recommendation that prescriptions for schedule 2, 3 & 4 controlled drugs (CDs) be limited to a quantity necessary for up to 30 days clinical need – affects prescribers, dispensing doctors, pharmacists and patients.

STARTING DATE: The arrangements will come into force on 1st April 2006 and, subject to Parliamentary Approval where required, will be given statutory backing in the Misuse of Drugs Regulations in early summer.

- Additional guidance will be issued to support the implementation of further amendments to the Misuse of Drugs regulations. This will include guidance on technical errors, recording ID of those collecting CDs on behalf of the patients (both public and professional) and broadening the groups of people entitled to witness the destruction of controlled drugs.

Introduction and Background

2 The Shipman Inquiry was set up on 31 January 2001 and was chaired by Lady Justice Janet Smith DBE as an independent public inquiry into the issues arising from the case of Harold Shipman. The Shipman Inquiry concluded that there were shortcomings in the systems used for the safe management of controlled drugs and made a number of recommendations to improve the management of such controlled drugs. The Inquiry found that there was no collection or monitoring of information around private prescribing and dispensing of controlled drugs in the community, and

concluded that this might be a significant loophole by which a person such as Shipman could exploit the system. The Governments response to the Inquiry's fourth report "Safer Management of Controlled Drugs" agreed that arrangements should be introduced to record and monitor information on private prescribing and dispensing of controlled drugs. It should be done in a similar way to current arrangements for NHS prescribed and dispensed controlled drug and should be done is such a way that does not impede on the appropriate use of CDs to meet patient need.

3 The Governments response also 'pledged' to undertake work to strengthened controls on the prescribing of controlled drugs more generally. Action is now in hand to incorporate these and other provisions in the Misuse of Drugs Regulations 2001, following a public consultation, which ended on 21 October 2005.

Purpose of this guidance

4 The purpose of this guidance is to inform relevant healthcare professionals and organisations about changes to the prescribing and dispensing of controlled drugs, in particular those prescribed privately. It is for the attention of:

- All prescribers, and in particular those prescribing CDs outside the NHS
- All community pharmacies and dispensing doctors
- PCT and SHA prescribing and pharmacy leads
- Patient representative organisations

STARTING DATE: The arrangements will come into force on 1st April 2006 and, subject to Parliamentary Approval where required, will be given statutory backing in the Misuse of Drugs Regulations in early summer.

New arrangements for private prescriptions

Summary

5 The new arrangements for private CD prescribers are as follows:

- Dedicated prescription forms are being introduced for non-NHS prescribing of schedule 2 & 3 CDs (FP10PCD);
- The Prescription Pricing Authority (PPA)[1] will allocate unique 6-digit private CD prescriber codes to doctors and other prescribers, eg nurses and pharmacists, who issue private prescriptions. This code will be different from the current NHS prescribers' codes. Private prescribers unique identifiers will all start with the number '6'. A prescriber who operates in the NHS and privately will, therefore, have two identifier codes (one NHS and one private).
- Each individual private CD prescriber will be assigned to a designated local NHS Primary Care Trust (PCT). The responsible PCT will generally be the one in whose geographic area the prescribers is registered or where most of the prescribing takes place;

[1] References to the PPA should be read as the Prescription Pricing Division of the NHS Business Services Authority from 1 April 2006.

- Private prescribers will obtain stocks of the new private prescription forms via their designated PCT and will use these forms for all their private prescribing of schedule 2 & 3 CDs;
- Pharmacists will send batches of the private prescription forms to the PPA for analysis on a monthly basis;
- PCTs will be responsible for monitoring private prescribers use of schedule 2 & 3 CDs, using information from the PPA analyses and other local information as appropriate;

Which prescriptions are affected?

6 Private prescriptions for schedule 2 & 3 CDs dispensed by community pharmacies and dispensing doctors in England, including hospital/clinic prescriptions for out-patients that are dispensed by a registered community pharmacy (including pharmacies without an NHS dispensing contract).

Administrative arrangements for private CD prescriptions

7 It is intended that the arrangements for private schedule 2 & 3 prescriptions will mirror those which are used more generally for NHS prescriptions. The Prescription Pricing Authority (PPA) will play a pivotal role in administering the arrangements. PPA will allocate the unique identifying code to each individual private prescriber and each community pharmacy dispensing such prescriptions. These identifying codes will provide the basis for monitoring the use of private schedule 2 & 3 prescriptions. Each private prescriber or their employing/hosting organisation will need to ensure their local PCT is aware that they issue private prescriptions for schedule 2 & 3 CDs. Each private prescriber of schedule 2 & 3 CDs will be assigned to a PCT in their local area. The PCT will arrange for the PPA to allocate the identifier(s) and initiate the issue of the special prescription forms to the prescriber(s). The prescriber or their employer will be invoiced for the cost of the prescription forms, which will be relatively modest.

8 The prescriber will be required to use these forms for schedule 2 & 3 CD prescriptions. Having completed the dispensing transaction, the community pharmacist will bundle the prescriptions each month and send them to PPA as they do for NHS prescriptions (please see footnote 2 for further details). The PPA will maintain a central record of prescriptions against individual prescribers. PCTs will be able to interrogate this record, to monitor prescribing or request retrieval of individual prescription forms. The central record will be a version of the current NHS e-PACT service.

9 In the interim period between 1st April 06 and the actual changes to the Medicines (sale or supply) (miscellaneous provisions) Regulations 1980 (expected in June 2006), community pharmacists should send a photocopy of the private prescriptions forms for schedule 2 & 3 CDs (FP10(PCD)) to the PPA and keep the original for their own records. This will ensure that the pharmacy satisfies the legislation as it stands at the moment. Once the legislation changes, pharmacists should send the original private prescription forms for schedule 2 & 3 CDs to the PPA (address provided at

footnote 2). Pharmacists may want to keep a copy of the FP10(PCD) for their own records.

Private CD Prescription Forms and Related Documents

10 Key changes are:

- A new special private CD prescription form, FP10PCD, for schedule 2 & 3 CDs, which will look like the example contained in Annex B;
- Introduction of a new private CD prescription FP34PCD dispensing submission document, for use by community pharmacies which dispense private prescriptions – an example is included in Annex D;

Implications for Private Prescribers

11 Each prescriber of private schedule 2 & 3 CDs will be issued with a unique code (6 digits beginning with the number '6') which will be printed on his/her prescriptions. The 6 digit number will be issued to private CD prescribers by the Prescription Pricing Authority (PPA). The Department of Health and the Healthcare Commission is initiating action to identify prescribers who conduct private practice, to establish whether they are affected by the introduction of these changes. **This includes NHS prescribers who prescribe CDs occasionally on a private basis, as some may do.**

12 Prescribers of private CDs will be required to prescribe schedule 2 & 3 CDs using the new prescription form (FP10PCD). The prescription pads will be ordered by the responsible PCT, and the private prescriber/organisation will be invoiced for their cost. This process will be decided at local level and the cost of the private prescription pads is expected to be modest.

13 The private CD prescription forms will be dispensed by a registered community pharmacy, which will in turn send the forms to the PPA for processing on a monthly basis. There will be no financial transaction with PPA, only the information on prescribing will be collected.

14 Subject to Parliamentary approval, paragraphs 10 to 12 will become statutory requirements and failure to comply may constitute a criminal offence.

15 As noted in paragraph 31 below, it is good practice and will in due course become mandatory, for all prescriptions for CDs including private prescriptions to include the patient's NHS number.

Please see Annex E for a decision tree diagram which should help you if you are a private prescriber.

Implications for Community Pharmacist

16 There will be significant changes in how community pharmacies handle private prescriptions for schedule 2 & 3 CDs. From 1 April 2006 community pharmacists should **not** dispense against a private prescription for schedule 2 & 3 CDs, unless it is on the designated form (FP10PCD, annex B). Prescriptions which are not on a designated form but are signed **before** 1st April 2006 can still be dispensed, as long as they are dispensed within the 13 weeks of the prescription being signed. If the prescription is signed **on** or **after** 1st April 2006 and is not on the designated form, it should not be accepted.

17 Each month the pharmacy will send the private CD prescription forms along with the new private CD prescription FP34PCD dispensary submission document to the PPA[2]. This will be a submission separate from and in addition to the usual NHS prescription forms. The PPA will process and record the information on its systems in order to inform the relevant PCT about private CD prescribing levels.

18 A private prescription for a schedule 2 or 3 controlled drug must be on a designated form. The community pharmacist must not dispense against a non-designated prescription. Additionally, the pharmacist should check that the patient's NHS number is clearly marked on the NHS or non-NHS prescription form. If the NHS number is not present, the pharmacist can still dispense against the form, provided s/he is satisfied that the prescription is legitimate. The pharmacist should also ask the patient to ensure their NHS number is present on the next occasion if at all possible.

Please see Annex F for a decision tree diagram which should help you if you are a community pharmacist who dispenses private prescriptions.

Implication for PCTs

19 PCTs will be responsible for monitoring the levels of CD prescribing for both NHS prescribers and for private CD prescribers. We expect PCTs to monitor private prescriptions of schedule 2 & 3 CDs in a similar way to their normal arrangements for monitoring NHS activity. The PPA ePACT system will provide each PCT with information relating to the private CD prescribers they have been assigned.

Please see Annex G for a decision tree diagram which should help you if you are a PCT dealing with private prescribers and community pharmacies that do not have an NHS contract.

Role of the Prescription Pricing Authority (PPA)

20 The PPA will receive batches of prescriptions from community pharmacies each month (separate batch of NHS prescriptions and separate batch of private CD prescriptions). The PPA processes each prescription by capturing the data provided

[2] Community pharmacies should continue to send the NHS prescription forms as they do now. Private schedule 2 & 3 CD prescription forms should be sent to: NHS/BSA Div 3 Newcastle, 3rd Floor, Cuthbert House, All Saints Business Centre, Newcastle upon Tyne, NE1 2ET.

on the prescription form, including information about the prescriber, the dispenser and the medication dispensed, including the quantity prescribed. The information will be recorded and then reported through a system, which will mirror the current ePACT service.

21 The PPA has conducted an exercise to identify registered community pharmacies that do not hold an NHS contract for pharmaceutical services. The PPA will be contacting all community pharmacies (both with and without an NHS contract) to allocate them with a unique identifier number for use when submitting private prescriptions.

22 The PPA will be issuing individual private prescribers with the unique private identifier. Initially, the PPA will be writing to the private prescribers directly (copied to the relevant PCT) with this information. Once this first tranche of private prescribers have been issued with their unique identifier, the PCTs will liaise with the PPA and pick up additional/future private prescribers as and when they need unique identifier numbers and thus private prescription pads for schedule 2 & 3 CDs.

23 The PPA will be assigning private prescribers to PCTs on an ongoing basis.

24 Please note that all references to the PPA within this document should be read as the Prescription Pricing Division of the NHS Business Services Authority from 1 April 2006.

The Role of the Healthcare Commission

25 The Healthcare Commission will have two distinct roles under the new arrangements:

i it will continue to be responsible for the regulation of the independent healthcare sector, including any use of CDs;

ii it will provide external assurance of all aspects of the new arrangements, including the systems set up by PCTs to ensure the safe management of CDs by all healthcare providers operating within their geographical area.

26 All registerable private healthcare providers are responsible for registering with the Healthcare Commission and for ensuring that they meet the requirements for registration. They will be expected to make an annual declaration saying whether or not they prescribe, supply or administer CDs to patients and those that do will be required to agree a Standing Operating Procedure (SOP) relating to their use of CDs. The Healthcare Commission will play a key role in resolving any practical issues arising from this guidance.

Patients

27 The new arrangements are designed to protect patients and improve patient

safety. Private prescribers should explain the requirements to patients **before** issuing a private prescription for a schedule 2 & 3 CD.

Changes affecting the dispensing of NHS and private prescriptions for CDs

28 Generally, community pharmacies will deal with NHS prescription forms (FP10) for schedule 2 & 3 CDs in the same way as now. However, NHS prescription forms (FP10) will include an additional declaration, for use when the patient or a person other than the patient collects a schedule 2 or 3 CD from the community pharmacy. An example of the new FP10 is included in Annex C. The new FP10 will be used when prescribing all products on the NHS, not just schedule 2 & 3 CDs. The introduction of these forms will be phased in on expiry of stocks of the old forms.

29 Any person collecting CDs against a schedule 2 prescription (both NHS and private) should be asked to provide evidence of his/her identity and to sign the back of the prescription form. Any person collecting CDs against a schedule 3 prescription (both NHS and private) should be asked to sign the back of the prescription form.

30 However, the pharmacist has discretion to supply the schedule 2 CDs to the patient or the patient's representative where no ID is presented. The pharmacist will also have discretion not to ask for ID if they feel that doing so may compromise patient confidentiality. If ID is not supplied, the pharmacist should record this in the CD register.

31 The contact details with regard to this guidance is private_prescribers@dh.gsi.gov.uk

ASSOCIATED ACTION TO MAINTAIN CONTROL OVER PRESCRIPTIONS FOR CDS IN THE COMMUNITY

Including patient identifiers on prescriptions for CDs

32 In future, as recommended by the Shipman Inquiry, all prescriptions for schedule 2 & 3 CDs, whether private or NHS, should include the patient's NHS number so that the usage of CDs by individual patients can be audited. Private prescribers should therefore ensure that they have a record of the patient's NHS number once they have determined that there is a clinical need for a schedule 2 & 3 CD prescription. This requirement is at present a matter of good practice but will in due course, subject to Parliamentary approval, become mandatory.

Validity of the length of prescriptions

33 The validity period of NHS and private prescriptions for Schedule 2, 3 & 4 controlled drugs will be restricted to 28 days. This means that the prescription should not be dispensed if more than 28 days have elapsed since it was signed and dated by the prescriber. The purpose of the change is to minimise the scope for prescription forms to be used if a significant time has elapsed since the clinical need was originally identified. This will become a mandatory requirement.

Prescribing for up to 30 days clinical need

34 In general, prescribers (both NHS and private) are strongly advised to restrict prescriptions for CDs to amounts no more than is sufficient to meet the patient's clinical need for up to 30 days supply. In exceptional circumstances, where the prescriber believes that a supply of more than 30 days is clinically indicated and would not pose an unacceptable risk to patient safety, the prescriber should make a note of the reasons in the patient's notes and should be ready to justify his/her decision if required.

Schedule 2 & 3 CD prescribing on an FP10 MDA (instalment prescriptions)

35 Arrangements for FP10MDA scripts continue as before, however the 28 day validity period applies to these scripts also. The 28 day period starts on the applicable date entered on the prescription form. This date will be the date of signing or a start date specified by the prescriber on the form. The first instalment must be dispensed within the 28 day limit, with the remainder instalments dispensed in accordance with the instructions. Patients are not required to sign for each instalment.

Re-issuing of medicines

36 Healthcare professionals are reminded that professional guidance strongly recommends that medicines returned from patient stocks should NOT be re-issued or used to treat other patients.

37 For pharmacists, the code of ethics prevents pharmacists reusing patient returns. A breach of this requirement could form the basis of disciplinary action.

Introduction of Standard Operating Procedures

38 All healthcare providers will be required to make an annual declaration as to whether they hold stocks of CDs on the premises. Those that do will be required by the relevant NHS regulations to comply with the terms of an agreed Standard Operating Procedure (SOP), which will be monitored as part of the new strengthened governance arrangements for CDs. Further guidance will be provided by the Department of Health in due course.

Prescriptions for self, close family and those close to the healthcare professional

39 The representative professional body of all healthcare professionals (ie, BMA, NMC, RSPGB etc) have their own code of conduct/standards/ethics with regard to the prescription of CDs for self, close family and those close to the healthcare professional. These should be read in conjunction with this

guidance and adhered to at all times.

Prescriptions for controlled drugs generated by computer.

40 From 14th November 2005, amendments to the Misuse of Drug Regulations (MDR) 2001 came into force which allow (a) all details on prescriptions for CDs except the signature to be computer generated (This removes the requirement that prescriptions for CDs must be handwritten) and (b) computarisation of CD registers for drugs listed in Schedules 1 and 2.

41 The Home Office have confirmed that technically the new legislative requirements for computer generated prescriptions for CDs do not prevent the use of pre-printed sticky labels on prescriptions. Good practice would require that if and where they are used, such sticky labels are tamper-evident should an attempt be made at their removal.

42 If a sticky label is used, prescribers should also sign on the sticky label or at least start their signature on the sticky label. This is a further guard to ensure sticky labels are not tampered with or another sticky label is not placed on top of the one that the prescribers signed for.

43 Also, whilst the new legal requirement allows all other details except the signature on the prescription to be written “in any form”, if these other details on the prescription are to be handwritten, good practice would dictate that they are hand written by an appropriate regulated healthcare professional. In addition, any manuscript changes to prescriptions (whether the original prescription was handwritten or computer generated) should be signed by the prescribers.

44 You can access full details of these changes and a copy of Statutory Instrument 2005 No 2864 by going to the Home Office website:

www.circulars.homeoffice.gov.uk and the HOC is numbered 48/2005.

Please see Annex A for more information on which drugs are classified in Schedule 2, 3 & 4 and the changes to the legislation.

Annex A

Legislation

The Misuse of Drugs Regulations (MDR) 2001 govern the possession and supply of the drugs controlled under the Misuse of Drugs Act 1971. The regulations also govern prescribing, safe custody, importation, exportation, production and record keeping. The Schedules define who may be in possession of or supply each drug, and under what conditions.

What are Schedule 2 & 3 Controlled Drugs

Controlled drugs are medicines used to treat a variety of clinical conditions, such as the relief of acute pain in myocardial infarction and the relief of severe chronic pain in palliative care. Schedule 2 & 3 controlled drugs are prescription only medicines and must be prescribed by a doctor or qualified non-medical prescriber.

They are subject to special legislative controls because of their potential for abuse or diversion . A list of Schedule 2 and Schedule 3 drugs can be found below:

SCHEDULE 2

Regulation 3

CONTROLLED DRUGS SUBJECT TO THE REQUIREMENTS OF REGULATIONS 14, 15, 16, 18, 19, 20, 21, 23, 26 AND 27

1. The following substances and products, namely -

Acetorphine	Levomoramide
Alfentanil	Levophenacylmorphan
Allylprodine	Levorphanol
Alphacetylmethadol	Lofentanil
Alphameprodine	Medicinal opium
Alphamethadol	Metazocine
Alphaprodine	Methadone
Anileridine	Methadyl acetate
Benzethidine	Methyldesorphine
Benzylmorphine (3-benzylmorphine)	Methyldihydromorphine
Betacetylmethadol	(6-methyldihydromorphine)
Betameprodine	Metopon
Betamethadol	Morpheridine
Betaprodine	Morphine

Bezitramide	Morphine methobromide, morphine N-oxide and
Carfentanil	other pentavalent nitrogen morphine derivatives
Clonitazene	Myrophine
Cocaine	Nicomorphine
Desomorphine	Noracymethadol
Dextromoramide	Norlevorphanol
Diamorphine	Normethadone
Diampromide	Normorphine
Diethylthiambutene	Norpipanone
Difenoxin	Oxycodone
Dihydrocodeinone	Oxymorphone
O-carboxymethyloxime	Pethidine
Dihydromorphine	Phenadoxone
Dimenoxadole	Phenampromide
Dimepheptanol	Phenazocine
Dimethylthiambutene	Phencyclidine
Dioxaphetyl butyrate	Phenomorphan
Diphenoxylate	Phenoperidine
Dipipanone	Piminodine
Dronabinol	Piritramide
Drotebanol	Proheptazine
Ecgonine, and any derivative of	Properidine
ecgonine which is convertible to	Racemethorphan
ecgonine or to cocaine	Racemoramide
Ethylmethylthiambutene	Racemorphan
Etonitazene	Sufentanil
Etorphine	Thebacon
Etoxeridine	Thebaine
Fentanyl	Tilidate
Furethidine	Trimeperidine
Hydrocodone	Zipeprol
Hydromorphinol	4-Cyano-2-dimethylamino-4,4-

Hydromorphone	diphenylbutane
Hydroxypethidine	4-Cyano-1-methyl-4-
Isomethadone	phenylpiperidine
Ketobemidone	2-Methyl-3-morpholino-1,1-diphenylpropane-
Levomethorphan	carboxylic acid
	α -Methylphenethylhydroxylamine
	1-Methyl-4-phenylpiperidine-4-carboxylic acid
	4-Phenylpiperidine-4-carboxylic acid ethyl ester

2. Any stereoisomeric form of a substance specified in paragraph 1 not being dextromethorphan or dextrorphan.

3. Any ester or ether of a substance specified in paragraph 1 or 2, not being a substance specified in paragraph 6.

4. Any salt of a substance specified in any of paragraphs 1 to 3.

5. Any preparation or other product containing a substance or product specified in any of paragraphs 1 to 4, not being a preparation specified in Schedule 5.

6. The following substances and products, namely -

Acetyldihydrocodeine	Methaqualone
Amphetamine	Methylamphetamine
Codeine	Methylphenidate
Dextropropoxyphene	Nicocodine
Dihydrocodeine	Nicodicodine (6-nicotinoyldihydrocodeine)
Ethylmorphine (3-ethylmorphine)	Norcodeine
Fenethylline	Phenmetrazine
Glutethimide	Pholcodine
Lefetamine	Propiram
Mecloqualone	Quinalbarbitone

7. Any stereoisomeric form of a substance specified in paragraph 6.

8. Any salt of a substance specified in paragraph 6 or 7.

9. Any preparation or other product containing a substance or product specified in any of paragraphs 6 to 8, not being a preparation specified in Schedule 5.

SCHEDULE 3

Regulation 3

CONTROLLED DRUGS SUBJECT TO THE REQUIREMENTS OF REGULATIONS 14, 15 (EXCEPT TEMAZEPAM), 16, 18, 22, 23, 24, 26 AND 27

1. The following substances, namely -

(a)

Benzphetamine	Mephentermine
Buprenorphine	Meprobamate
Cathine	Methylphenobarbitone
Chlorphentermine	Methyprylone
Diethylpropion	Pentazocine
Ethchlorvynol	Phendimetrazine
Ethinamate	Phentermine
Flunitrazepam	Pipradrol
Mazindol	Temazepam

(b) any 5, 5 disubstituted barbituric acid not being quinalbarbitone.

2. Any stereoisomeric form of a substance specified in paragraph 1 not being phenylpropanolamine.

3. Any salt of a substance specified in paragraph 1 or 2.

4. Any preparation or other product containing a substance specified in any of paragraphs 1 to 3, not being a preparation specified in Schedule 5.

SCHEDULE 4

Regulation 3

PART I

CONTROLLED DRUGS SUBJECT TO THE REQUIREMENTS OF REGULATIONS 22, 23, 26 AND 27

1. The following substances and products, namely -

Alprazolam	Ketazolam
Aminorex	Loprazolam
Bromazepam	Lorazepam

Brotizolam	Lormetazepam
Camazepam	Medazepam
Chlordiazepoxide	Mefenorex
Clobazam	Mesocarb
Clonazepam	Midazolam
Clorazepic acid	Nimetazepam
Clotiazepam	Nitrazepam
Cloxazolam	Nordazepam
Delorazepam	Oxazepam
Diazepam	Oxazolam
Estazolam	Pemoline
Ethyl loflazepate	Pinazepam
Fencamfamin	Prazepam
Fenproporex	Pyrovalerone
Fludiazepam	Tetrazepam
Flurazepam	Triazolam
Halazepam	*N*-Ethylamphetamine
Haloxazolam	

2. Any stereoisomeric form of a substance specified in paragraph 1.

3. Any salt of a substance specified in paragraph 1 or 2.

4. Any preparation or other product containing a substance or product specified in any of paragraphs 1 to 3, not being a preparation specified in Schedule 5.

PART II

CONTROLLED DRUGS EXCEPTED FROM THE PROHIBITION ON POSSESSION WHEN IN THE FORM OF A MEDICINAL PRODUCT; EXCLUDED FROM THE APPLICATION OF OFFENCES ARISING FROM THE PROHIBITION ON IMPORTATION AND EXPORTATION WHEN IMPORTED OR EXPORTED IN THE FORM OF A MEDICINAL PRODUCT BY ANY PERSON FOR ADMINISTRATION TO HIMSELF; AND SUBJECT TO THE REQUIREMENTS OF REGULATIONS 22, 23, 26 AND 27

1. The following substances, namely -

Atamestane	Methenolone
Bolandiol	Methyltestosterone

Bolasterone	Metribolone
Bolazine	Mibolerone
Boldenone	Nandrolone
Bolenol	Norboletone
Bolmantalate	Norclostebol
Calusterone	Norethandrolone
4-Chloromethandienone	Ovandrotone
Clostebol	Oxabolone
Drostanolone	Oxandrolone
Enestebol	Oxymesterone
Epitiostanol	Oxymetholone
Ethyloestrenol	Prasterone
Fluoxymesterone	Propetandrol
Formebolone	Quinbolone
Furazabol	Roxibolone
Mebolazine	Silandrone
Mepitiostane	Stanolone
Mesabolone	Stanozolol
Mestanolone	Stenbolone
Mesterolone	Testosterone
Methandienone	Thiomesterone
Methandriol	Trenbolone

2. Any compound (not being Trilostane or a compound for the time being specified in paragraph 1 of this Part of this Schedule) structurally derived from 17-hydroxyandrostan-3-one or from 17-hydroxyestran-3-one by modification in any of the following ways, that is to say -

(a) by further substitution at position 17 by a methyl or ethyl group;

(b) by substitution to any extent at one or more of positions 1, 2, 4, 6, 7, 9, 11 or 16, but at no other position;

(c) by unsaturation in the carbocyclic ring system to any extent, provided that there are no more than two ethylenic bonds in any one carbocyclic ring;

(d) by fusion of ring A with a heterocyclic system.

3. Any substance which is an ester or ether (or, where more than one hydroxyl function is available, both an ester and an ether) of a substance specified in paragraph 1 or described in

paragraph 2 of this Part of this Schedule.

4. The following substances, namely -

Chorionic Gonadotrophin (HCG)

Clenbuterol

Non-human chorionic gonadotrophin

Somatotropin

Somatrem

Somatropin

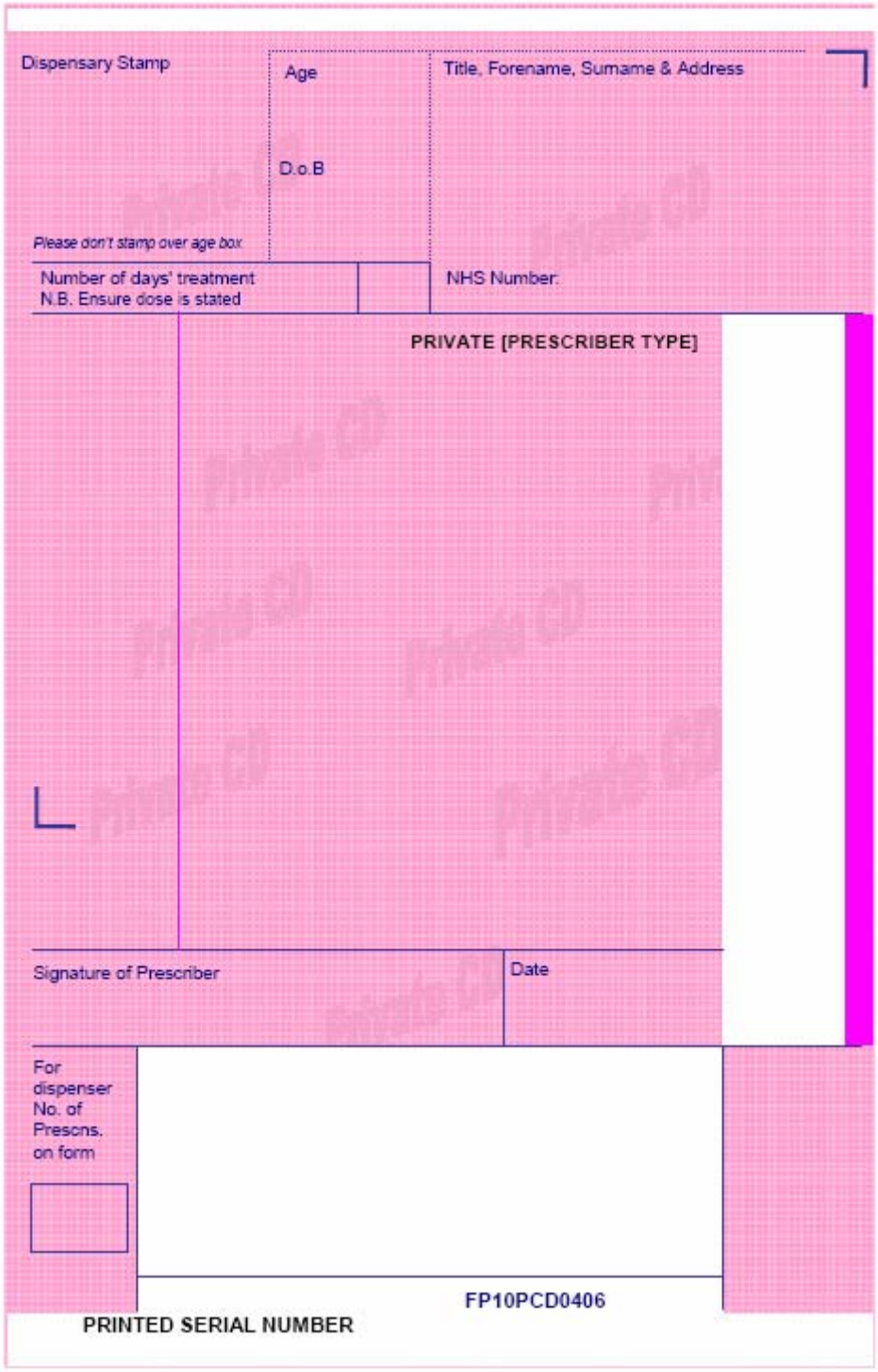
5. Any stereoisomeric form of a substance specified or described in any of paragraphs 1 to 4 of this Part of this Schedule.

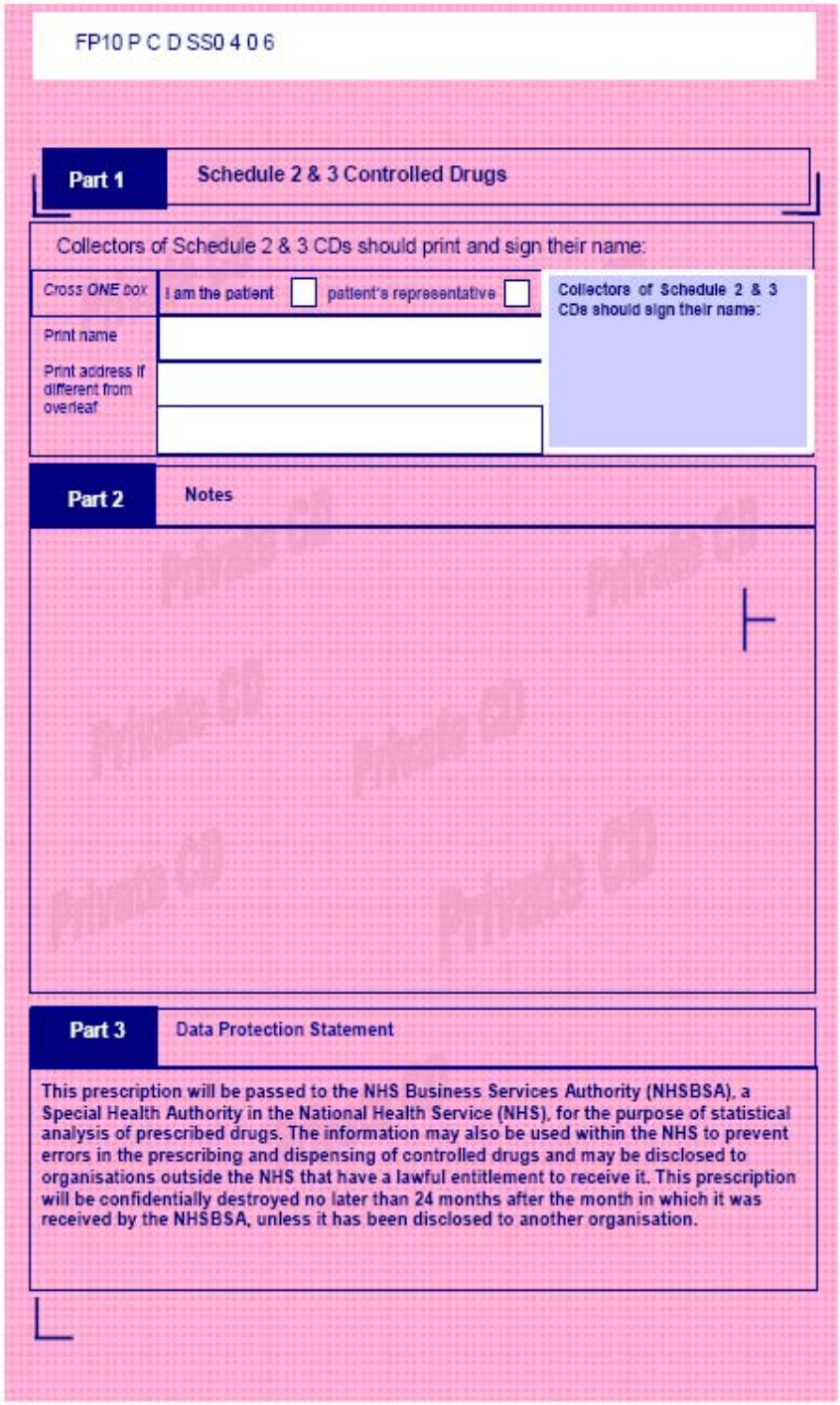
6. Any salt of a substance specified or described in any of paragraphs 1 to 5 of this Part of this Schedule.

7. Any preparation or other product containing a substance or product specified or described in any of paragraphs 1 to 6 of this Part of this Schedule, not being a preparation specified in Schedule 5.

Annex B

New schedule 2 & 3 Controlled Drugs Private Prescription Form - Front





FP10 P C D SS0 4 0 6

Part 1 Schedule 2 & 3 Controlled Drugs

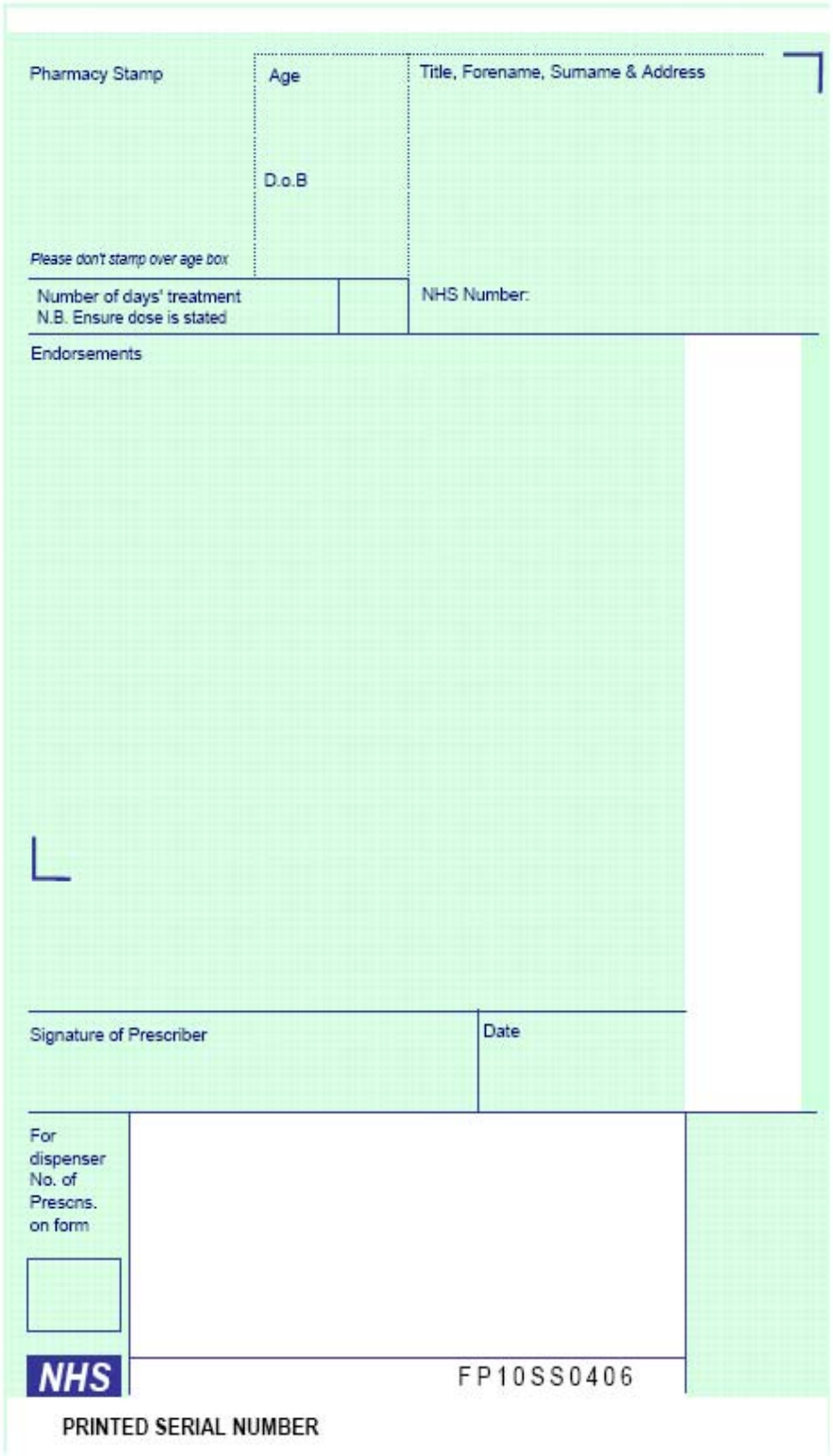
Collectors of Schedule 2 & 3 CDs should print and sign their name:

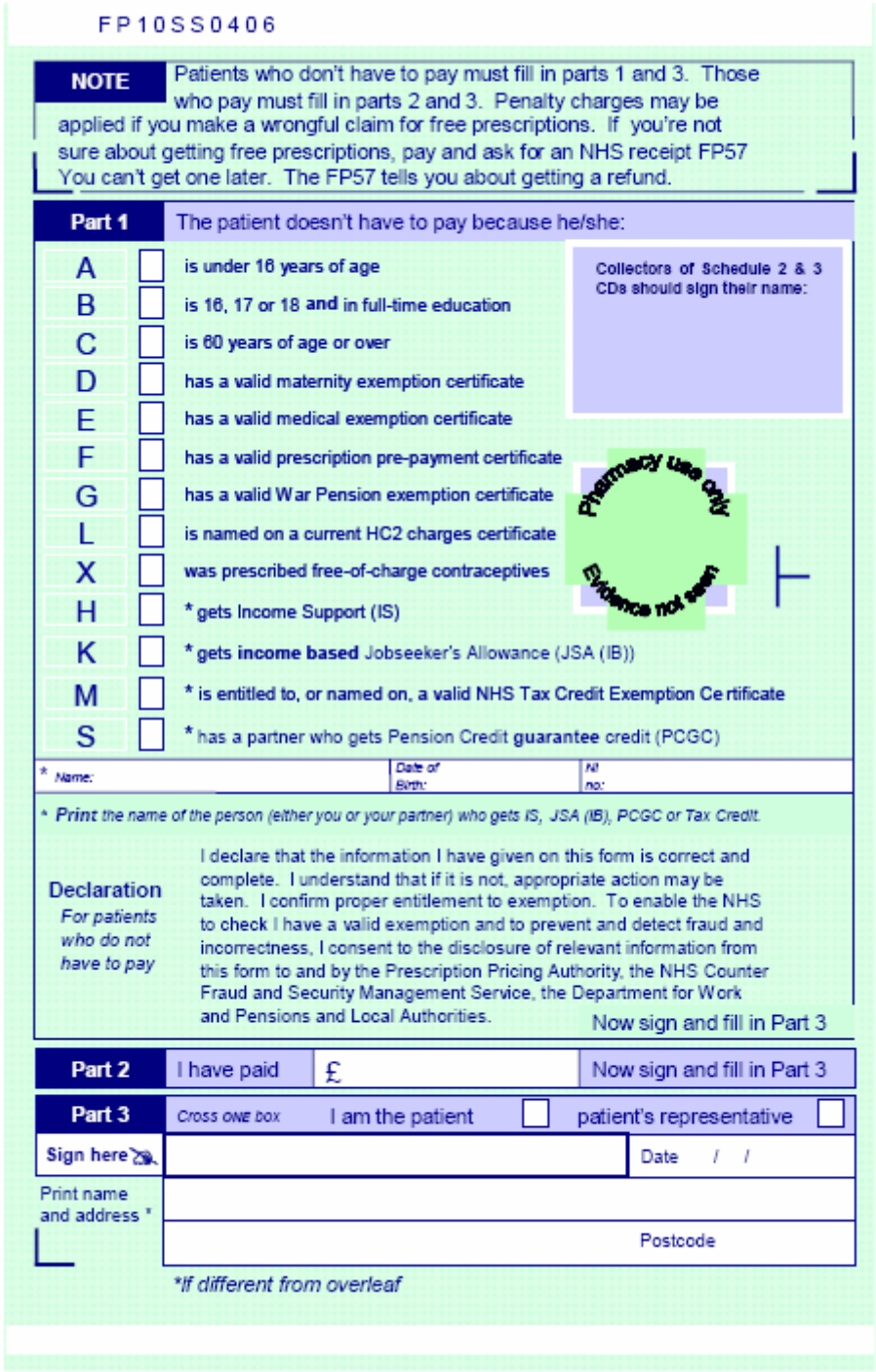
Cross ONE box	I am the patient ☐	patient's representative ☐	Collectors of Schedule 2 & 3 CDs should sign their name:
Print name			
Print address if different from overleaf			

Part 2 Notes

Part 3 Data Protection Statement

This prescription will be passed to the NHS Business Services Authority (NHSBSA), a Special Health Authority in the National Health Service (NHS), for the purpose of statistical analysis of prescribed drugs. The information may also be used within the NHS to prevent errors in the prescribing and dispensing of controlled drugs and may be disclosed to organisations outside the NHS that have a lawful entitlement to receive it. This prescription will be confidentially destroyed no later than 24 months after the month in which it was received by the NHSBSA, unless it has been disclosed to another organisation.


Pharmacy Stamp
Age
D.o.B
Please don't stamp over age box
Title, Forename, Surname & Address
Number of days' treatment
N.B. Ensure dose is stated
NHS Number:
Endorsements
Signature of Prescriber
Date
For dispenser No. of Prescns. on form
NHS
FP10SS0406
PRINTED SERIAL NUMBER



FP10SS0406

NOTE Patients who don't have to pay must fill in parts 1 and 3. Those who pay must fill in parts 2 and 3. Penalty charges may be applied if you make a wrongful claim for free prescriptions. If you're not sure about getting free prescriptions, pay and ask for an NHS receipt FP57 You can't get one later. The FP57 tells you about getting a refund.

Part 1 The patient doesn't have to pay because he/she:

A	☐	is under 16 years of age
B	☐	is 16, 17 or 18 **and** in full-time education
C	☐	is 60 years of age or over
D	☐	has a valid maternity exemption certificate
E	☐	has a valid medical exemption certificate
F	☐	has a valid prescription pre-payment certificate
G	☐	has a valid War Pension exemption certificate
L	☐	is named on a current HC2 charges certificate
X	☐	was prescribed free-of-charge contraceptives
H	☐	* gets Income Support (IS)
K	☐	* gets **income based** Jobseeker's Allowance (JSA (IB))
M	☐	* is entitled to, or named on, a valid NHS Tax Credit Exemption Certificate
S	☐	* has a partner who gets Pension Credit **guarantee** credit (PCGC)

Collectors of Schedule 2 & 3 CDs should sign their name:

Pharmacy use only. Evidence not seen

* Name:	Date of Birth:	NI no:

* *Print the name of the person (either you or your partner) who gets IS, JSA (IB), PCGC or Tax Credit.*

Declaration *For patients who do not have to pay*

I declare that the information I have given on this form is correct and complete. I understand that if it is not, appropriate action may be taken. I confirm proper entitlement to exemption. To enable the NHS to check I have a valid exemption and to prevent and detect fraud and incorrectness, I consent to the disclosure of relevant information from this form to and by the Prescription Pricing Authority, the NHS Counter Fraud and Security Management Service, the Department for Work and Pensions and Local Authorities.

Now sign and fill in Part 3

Part 2 I have paid £ Now sign and fill in Part 3

Part 3 *Cross one box* I am the patient ☐ patient's representative ☐

Sign here Date / /

Print name and address *

Postcode

**If different from overleaf*

Annex D

FP34PCD0406 (Private CD Prescriptions)	Submission Document

Part 1 Submissions

	Forms	Items
(Private Controlled Drug Prescriptions)		

Part 2 Contractor Details and Authorisation

Contractor's Name and Address	Contractor's Stamp

Please fold here

A/C Type	A/C ID	Year	Month
EPHM		2006	APRIL

Signed: _ _ _ _ _ _ _ _ _ _ _ _ _ _ _ _

Date: _ _ _ _ _ _ _ _ _ _ _ _ _ _ _ _

Please fold here

FP34PCD0406 (Private CD Prescriptions)	Submission Document

INTERIM GUIDANCE

SORTING AND SUBMISSION OF FORMS

1. Complete one submission document only, include the contractor stamp in the space provided.

2. Within each submission, sort all FP10 forms by prescriber name.

3. Enter the required submission figures in the boxes overleaf. Please note that any figures written in this area should be right-justified.

Example:

		1	2	3

4. Please fold this submission document along the 2 printed fold lines, so that your A/C ID is visible on the top. Place this completed submission document on top of the FP10PCD forms, pack securely and dispatch to the NHS Business Services Authority (NHS/BSA) by NO LATER THAN the FIFTH day of the month following which they were supplied.

NHS/BSA Div 3 Newcastle
3rd Floor
Cuthbert House
All Saints Business Centre
Newcastle upon Tyne
NE1 2ET

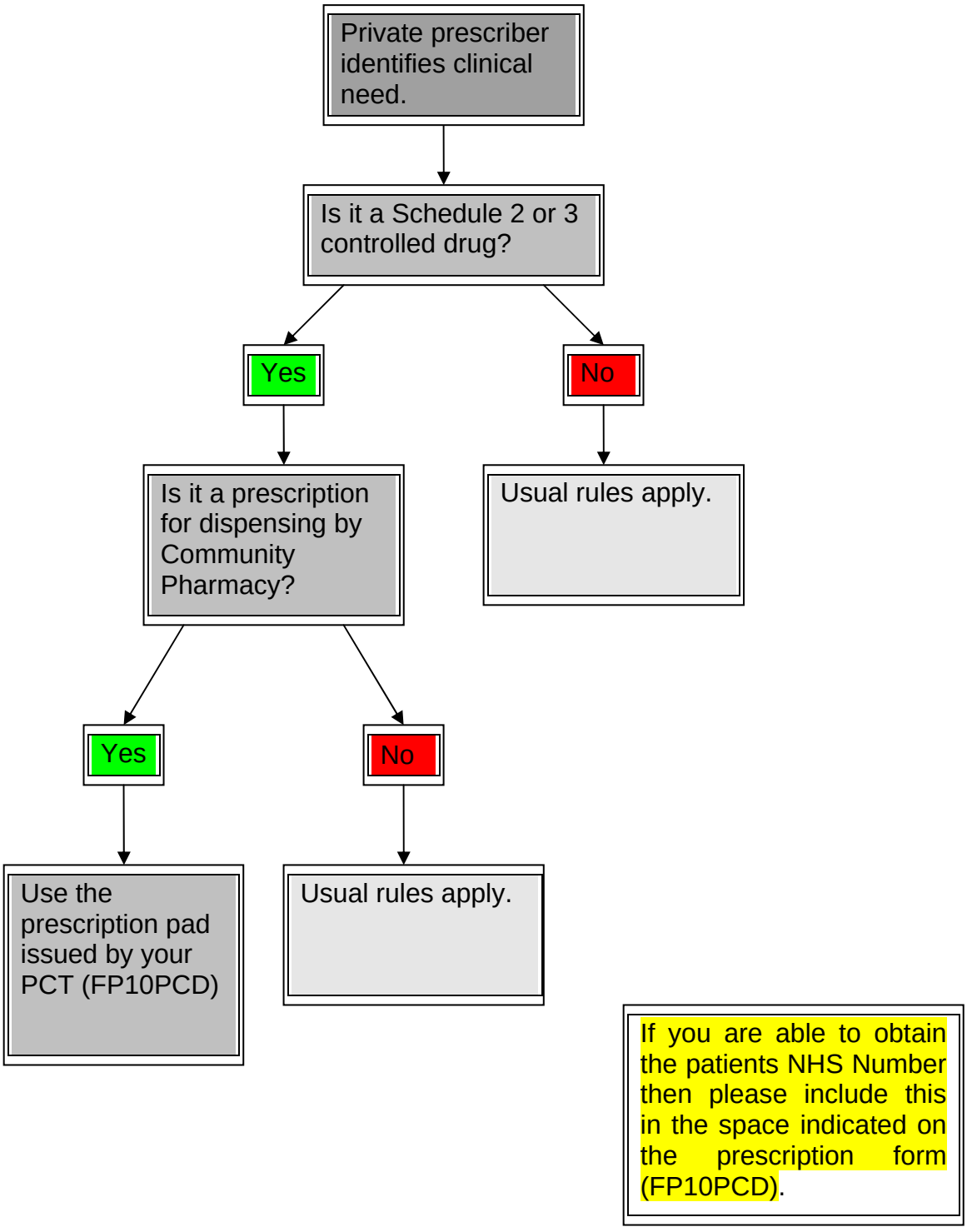
5. Do not enclose any documents not related to the submission of schedule 1, 2 and 3 private controlled drug prescription forms (FP10PCD) with this submission.

NOTES

a) PLEASE DO NOT use adhesive tape, pins or staples, as these have to be removed on receipt and can seriously delay processing
b) Postage on parcels and correspondence sent to the NHS/BSA MUST be pre-paid

Annex E

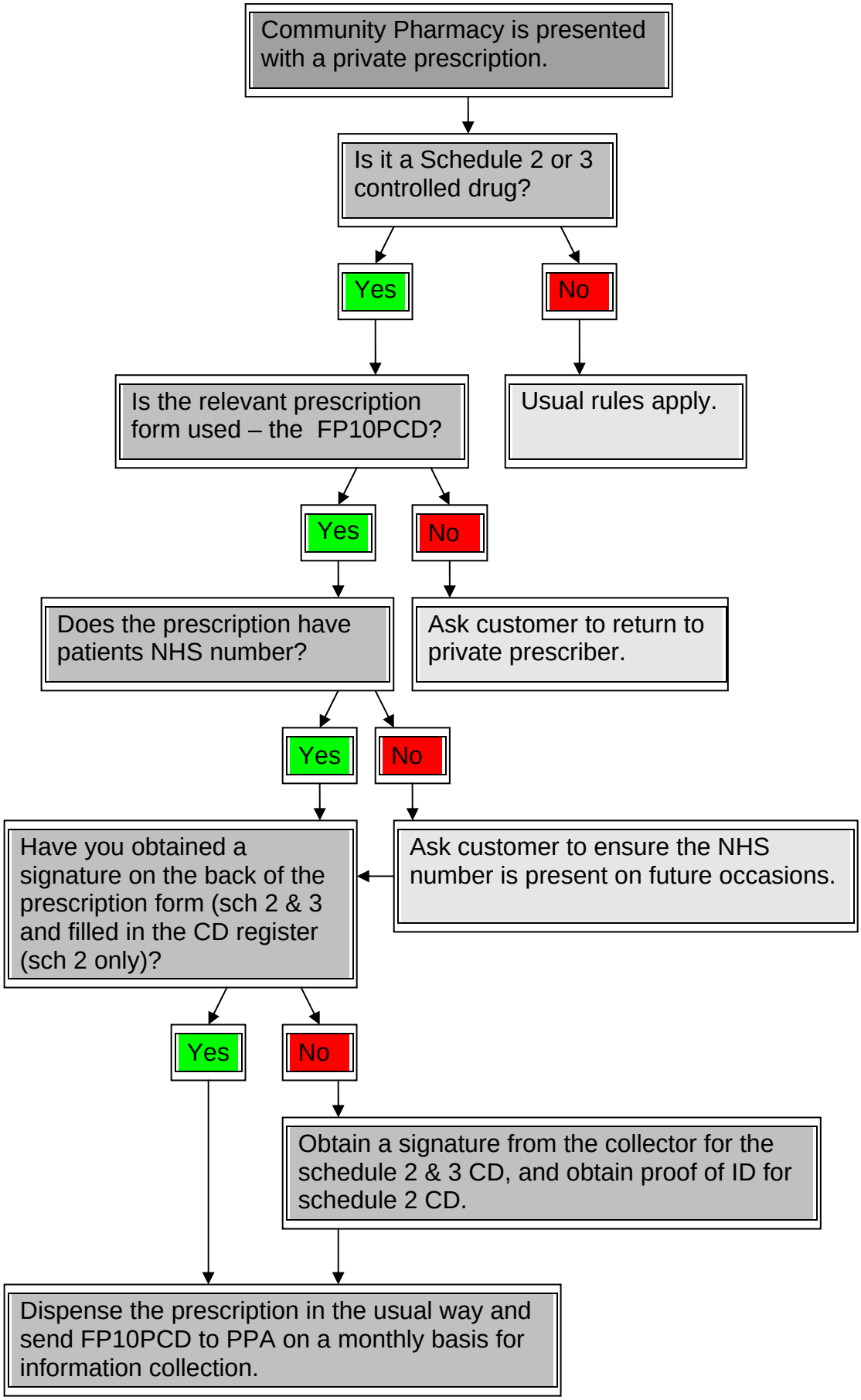
Decision tree for private prescribers of schedule 2 and 3 controlled drugs



INTERIM GUIDANCE

Annex F

Decision tree for Community Pharmacies when presented with a private prescription



Decision tree for Primary Care Trusts when they have been notified that they have a private prescribers/organisation and/or Community Pharmacy that does not have an NHS dispensing contract (to monitoring controlled drugs activity) in their geographical area.