# EXPLANATORY MEMORANDUM TO THE MISUSE OF DRUGS AND THE MISUSE OF DRUGS (SUPPLY TO ADDICTS) (AMENDMENT) REGULATIONS 2005

## 2005 No.2864

**1.** This explanatory memorandum has been prepared by the Home Office and is laid before Parliament by Command of Her Majesty.

## 2. Description

2.1 This instrument amends the Misuse of Drugs Regulations 2001 ("the 2001 Regulations") and makes a consequential amendment to the Misuse of Drugs (Supply to Addicts) Regulations 1997. It contains amendments in five different policy areas:

2.2 Measures to computerise prescriptions and registers;

2.3 Measures to enable certain records to be stored and furnished electronically;

2.4 Measures to allow specialist nurses called Extended Formulary Nurse Prescribers to prescribe, administer and supply a number of controlled drugs for patients for certain specified purposes and medical conditions without first obtaining permission from a doctor;

2.5 Measures to allow ascorbic acid to be used as an additional item of drug paraphernalia;

2.6 Measures to remove 0.1% cocaine preparation from the exception from the prohibition on importation and exportation.

## 3. Matters of special interest to the Joint Committee on Statutory Instruments

3.1 None.

## 4. Legislative Background

4.1 The instrument is made under sections 7, 10, 22 and 31 of the Misuse of Drugs Act 1971. That Act received Royal Assent on 27 May 1971. Section 31(3) of the Misuse of Drugs Act 1971 provides that the Secretary of State may not make regulations under that Act except after consultation with the Advisory Council on the Misuse of Drugs (ACMD). The ACMD has considered these proposals and has recommended that the proposed changes be implemented.

## 5. Extent

5.1 This instrument applies to all of the United Kingdom.

## 6. European Convention on Human Rights

6.1 As the instrument is subject to negative resolution procedure and does not amend primary legislation, no statement is required.

## 7. Policy Background

Amendment A - Computer-Generated Prescriptions

7.1 The 2001 Regulations are amended to allow all details on prescriptions for Schedule 2 and 3 controlled drugs, apart from the signature, to be generated by computer. Currently, certain details on a prescription must be specified in the prescriber's own handwriting. In practice, exemption certificates are issued to doctors working as members of, or in conjunction with, a drug dependency unit or a community drugs team and there are over 2,000 current handwriting exemption certificates on issue. Doctors currently computer-generate their regular prescriptions for medicines that are not controlled drugs and for Schedule 4 and 5 drugs, and it is now appropriate that they be allowed to do so for all controlled drugs**.** GP computer systems have security safeguards to prevent prescriptions from being altered or forged. As set out in *Safer Management of Controlled Drugs* the Government's response to the Fourth Report of the Shipman Inquiry, the Government now consider there is little risk in relaxing the handwriting requirements, with the exception of the signature, for controlled drug prescriptions.

Computerised Registers

7.2 The 2001 Regulations will be amended to allow controlled drug (CD) registers for Schedule 1 and 2 drugs to be maintained and preserved on computer. Currently, persons authorised to supply these drugs (e.g. doctors and manufacturers) are required to keep a register and enter in it details of all Schedule 1 and 2 drugs obtained or supplied. The register must be in the form of a bound book and must be in a specified format and must be available for inspection. The rules concerning CD registers are aimed at providing a tight audit trail of supplies of Schedule 1 and 2 drugs. The register-keeping requirements are quite onerous, particularly for major producers and distributors of Schedule 2 drugs as they make many supplies each day.

7.3 An amendment has been made to the 2001 Regulations to permit pharmacists, doctors, dentists, vets and certain other persons to keep records of Schedule 1 and 2 drugs in the required format either in a bound register or on computer. The Drugs Inspectorate consider that computerised registers would be more useful than manual records as the former would enable Drugs Inspectors to trace individual consignments of drugs more readily. Computerised registers also facilitate maintenance of a running balance of stock, currently a matter of good practice. *Safer Management of Controlled Drugs* made clear the Government intends, subject to Parliamentary approval,

to make inclusion of a running balance a mandatory requirement once computerised registers are in common use.

Preservation of Registers and Records

7.4 Regulations 22, 23 and 24 of the 2001 Regulations provide that registers for Schedule 1 and 2 drugs, and certain records relating to Schedule 3, 4 and 5 drugs, must be preserved for two years. Manufacturers, wholesalers and pharmacists are also required to keep every requisition, order and private prescription against which a controlled drug is supplied for two years. In addition, certain other persons are required to keep for two years invoices or similar records relating to all Schedule 3 and 5 drugs that are obtained and supplied. At present, the original register, requisition, order and private prescription must be preserved. The 2001 Regulations permit the keeping of copies of invoices, but it is not explicit that they allow such records to be held on computer, or archived by any other means (e.g. microfiche or disk).

7.5 The requirements relating to the preservation of requisitions, orders and private prescriptions are now amended to allow the information they contain to be preserved in original form, or as a copy on computer. The amendment covers the provisions governing the preservation of invoices to allow the information they contain to be held on computer.

Amendment B - Extended Formulary Nurse Prescribers

7.6 Since April 2002, the Department of Health has allowed Extended Formulary Nurse Prescribers to independently prescribe a large number of prescription only medicines for patients without obtaining permission from a doctor. The Misuse of Drugs (Amendment) (No.3) Regulation 2003 (SI No: 2003/2429) which came into force on 15 October 2003 amended the Misuse of Drugs Regulations 2001 to give such nurses the power to prescribe six controlled drugs in restricted circumstances:

(a) diazepam, lorazepam and midazolam (which are listed as Schedule 4 drugs in the 2001 Regulations) - for use in palliative care only; and

(b) codeine phosphate, dihydrocodeine tartrate and co-phenotrope (which qualify as Schedule 5 drugs in the 2001 Regulations).

7.7 The amendments made by regulations 3 and 5 to 8 of this instrument allow the following drugs controlled under the Misuse of Drugs Act 1971 to be added to the Nurse Prescribers Extended Formulary to be prescribed, administered and supplied solely for the medical condition indicated below:

- For pain relief in respect of suspected myocardial infarction or for relief of acute or severe pain after trauma including in either case post-operative pain relief:
  Diamorphine
  Morphine

- For use in palliative care:
  Diamorphine
  Morphine
  Oxycodone
  .
- For transdermal use in palliative care:
  Buprenorphine
  Fentanyl

- For treatment of initial or acute withdrawal symptoms caused by the withdrawal of alcohol from persons habituated to it:
  Chlordiazepoxide hydrochloride
  Diazepam

Amendment C – Ascorbic Acid

7.8 The Misuse of Drugs (Amendment) (No.2) Regulation 2003 (SI. No 2003/1653) which came into force on 1 August 2003 inserted regulation 6A into the 2001 Regulations to give doctors, pharmacists and persons employed or engaged in the lawful provision of drug treatment services the authority to supply certain items of drug injecting articles (known as "paraphernalia") to drug users. The paraphernalia listed in regulation 6A includes swabs, utensils for the preparation of a controlled drug, citric acid, filters and ampoules of water for injection. Subsequent evidence provided to the ACMD has shown that addicts who inject crack or freebase cocaine tend to use ascorbic acid rather than citric acid. This amendment is aimed at reducing the level of harm that addicts face when choosing an acidifier to use for injecting crack or "freebase" cocaine.

Amendment D - Removal of 0.1% Cocaine Preparation

7.9 This amendment removes paragraph 2 of Schedule 5 to the 2001 Regulations. Police and Customs currently spend approximately £30,000 per annum analysing preparations of cocaine to establish whether they contain less than 0.1% of the drug. Where they contain less than 0.1% cocaine, they are excepted from the prohibition on importation, exportation and possession and subject to the requirements in regulation 24 and 26 of the 2001 Regulations. Although this analysis is carried out to test the purity of the cocaine to assist the court with sentencing, it is often only requested in order to decide whether or not to proceed with a prosecution. This means, without this change, there is a lot of additional analytical work carried out by FSS annually, disproportionate to the cost involved to the Police and Customs.

## 8. Impact

8.1 A Regulatory Impact Assessment has been prepared by the Home Office in conjunction with the Department of Health that describes the effect of the proposals on the healthcare sector and police and highlights the potential costs in terms of administration.

8.2 The Regulatory Impact Assessment states that the amended regulations will not impose substantial additional costs on the NHS or small businesses such as pharmacies but provide instead considerable savings in terms of both cost and time. It will also be of benefit in terms of improving patient care.

8.3 There are no resource implications for the Home Office.

## 9. Contact for inquiries

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# FINAL REGULATORY IMPACT ASSESSMENT

1. COMPUTER GENERATED PRESCRIPTIONS, REGISTERS AND RECORD KEEPING FOR CONTROLLED DRUGS – Amendment to the Misuse of Drugs Regulations 2001:

2. EXTENSION OF PROVISIONS FOR EXTENDED FORMULARY NURSE PRESCRIBERS – Amendment to Misuse of Drugs Regulations 2001:

3. ADDITION OF ASCORBIC ACID TO LIST OF ALLOWABLE PARAPHERNALIA ITEMS – Amendment to the Misuse of Drugs Regulations 2001:

4. REMOVAL OF REFERENCE TO 0.1% PREPARATION OF COCAINE IN SCHEDULE 5 – Amendment to the Misuse of Drugs Regulations 2001:

## 1. PURPOSE, INTENDED EFFECT, OPTIONS & BENEFITS

**Proposal 1 – Prescriptions for Controlled Drugs**

Issue

1.1 Regulation 15 (1) of the Misuse of Drugs Regulations 2001 (The 2001 Regulations) provides that certain details on prescriptions for controlled drugs should be written by prescribers in their own handwriting. The handwriting condition was introduced in 1973 in order to reduce the risk of diversion of controlled drugs (CDs) through forgery or alteration of prescriptions. The own handwriting requirement was intended to ensure the prescriber personally wrote prescriptions for drugs, making prescriptions more difficult to tamper with.

1.2 The following details are required to be in the prescriber's own handwriting:

- the patient's name and address;
- the dose to be taken;
- the form of the drug (e.g. tablets, capsules etc) and, where appropriate, the strength; and
- the total quantity, in both figures and words, of the preparation or the total number of dose units to be supplied.

1.3 The handwriting requirements apply to all prescriptions for Schedule 2 and 3 drugs, unless the prescriber has been exempted from them by virtue of a handwriting exemption certificate issued by the Home Office under Regulation 15 (2), or where the drug prescribed is phenobarbitone. Temazepam has been specifically exempted from all Regulation 15 requirements.

Objective

1.4 The proposal is to remove the handwriting restriction so that all details on such prescriptions can be printed, or generated on computer or continue to be hand-written (with the exception of the signature which must still be in the prescriber's own handwriting). The use of computer technology to write prescriptions will significantly ease the burden on practitioners and pharmacists and reduce the possibility of hand-written prescriptions being misread.

1.5 In practice, doctors have for many years been able to computer-generate their regular prescriptions for all medicines that are not Schedule 2 or 3 controlled drugs. (Examples of the types of drugs found in the different schedules can be found at Annex A). This system has worked well over the years and due to recent developments in information technology and software packages that record alterations, the Government now considers that the handwriting requirement should be relaxed for all controlled drug prescriptions.

Options

1.6 Two options have been identified:

Option 1 - do nothing. The risks involved in pharmacists having to decipher a doctors handwriting will continue, with the potential for mistakes to be made and time wasted in seeking clarification.

Option 2 - amend the law as proposed to give more flexibility in allowing the relevant details on such prescriptions to be hand-written, or printed or generated by computer. This will lead to fewer technical prescribing errors and a decrease in the number of prescriptions referred back to prescribers for rewriting. This will also reduce the number of occasions when patients have to wait for their prescriptions.

Economic and Social Benefits

1.7 Option 1 – None. Prescribers (i.e. doctors, dentists and vets) would continue to be bound by the handwriting requirements for the relevant prescriptions and pharmacists would continue to have problems in deciphering the hand-written instructions before dispensing the relevant medicines to patients.

1.8 Option 2 - This option would allow prescribers to use computer technology to print all details on such prescriptions (except for the signature). The prescribes would no longer be required to complete all the details in their own handwriting, thus reducing consulting times. There are currently about 32,000 doctors working in the NHS and the actual time saved by each individual doctor will vary. However, each consultation with

a patient has been shown to take approximately 9 minutes. This option would allow prescribers to use forms pre-filled with the patient's details. This would save them the amount of time taken to fill in the form by hand, as they can now simply print it off and sign it. In addition it has been calculated that a minute of a GP's time in the surgery amounts to £2.24 (Unit Costs of Health and Social Care 2003/4). There is certainly a potential saving of between 15-30 seconds for each computerised prescription. About 3,700,000 prescriptions written annually (figures for 2003/2004) are for schedule 2/3 controlled drugs so the savings could be considerable, although it has been agreed by all parties consulted that providing an actual figure is not possible. Based on the above figures the measure could yield a cost saving of between £2.07M and £4.14M annually. These figures include prescriptions from dentists. Prescriptions written by vets for schedule 2/3 drugs are very low.

1.9 4,800 nurses called "supplementary prescribers" are able to prescribe controlled drugs in partnership with a doctor. It is understood that by Autumn 2005 nurse prescribers working in GP's surgeries are likely to generate their own prescriptions using their practices' software. This will result in time savings for the nurse prescriber and increase patient safety by eliminating human error and handwriting enquiries from the pharmacist. Although it is difficult to quantify the cost savings, savings in terms of nurse prescribers time is likely to be in the region of several thousand hours a year.

1.10 These measure will also allow pharmacists to dispense prescription more quickly as reading the details will be easier if they are printed thus reducing the number of occasions querying the details with prescribers. Consequently, such time savings would also be of benefit to patients. A further benefit would be the reduction of potentially dangerous mistakes being made due to the misreading the prescriptions. However, it should be noted that these are qualitative benefits only as there is no readily available data which can accurately quantify these benefits.

**Proposal 1B – Registers for Controlled Drugs**

Issue

1.11 Regulations 19 and 20 of the 2001 Regulations require that all persons authorised to supply Schedule 1 and 2 drugs must record in a register in indelible ink details of all such drugs which they have obtained or supplied in a particular format. The persons authorised include licensed pharmaceutical manufacturers and wholesalers, pharmacists, doctors, dentists and vets. "Register" is defined as a bound book and does not include any form of loose-leaf register or card index. The planned Department of Health Electronic Transmission of Prescriptions (ETP) programme is currently being rolled out to a small number of implementer sites. ETP will use the NHSnet to link all computerised GP practices to local community pharmacies. Both groups would then link in to the Prescription Pricing Authority (PPA). £58 million has been earmarked by

DH as a contribution to increased IT costs as a result of the introduction of ETP.

Objective

1.12 The proposal is to amend Regulations 19 and 20 to allow the authorised persons the flexibility to keep records of Schedule 1 and 2 drugs in the required format *either* in a bound register *or* on computer. The use of computerised registers will be subject to safeguards being incorporated into the software to ensure that entries could not be altered at a later date.

Options

1.13 Two options have been identified:

Option 1 – do nothing.

Option 2 – amend the law as proposed to give more flexibility in allowing such records to be kept in the required format either in a bound book or on computer.

Economic and Social Benefits

1.14 Option 1 – None. The requirement to keep manual records on registers for the relevant drugs will remain, thus preventing the relevant persons (e.g. pharmacists, doctors, dentists, vets, producers, wholesalers) from having a choice of keeping such records electronically.

1.15 Option 2 - The requirement to keep manual records on registers is quite onerous, particularly for major commercial producers and suppliers of such drugs who have to record a large number of transactions every day. The flexibility of allowing such records to be computerised would produce significant time savings, not only for producers and suppliers but also for doctors and pharmacists. Enforcement bodies (e.g. Home Office Drugs Inspectors) would also find it easier to trace individual consignments of drugs more readily if the records are kept in computerised rather than manual form. With the introduction of ETP, a connecting system between GPs and pharmacies will have obvious benefits in terms of patient care. In addition, an electronic register linked to running balances will give pharmacists greater reassurance when dispensing CDs and allow more time for them to be involved in the clinical process within the community.

**Proposal 1C – Other Record Keeping Requirements for Controlled Drugs**

Issue

1.16 Regulations 22, 23 and 24 of the 2001 Regulations provide that registers for Schedule 1 and 2 drugs and certain records relating to Schedule

3, 4 and 5 drugs, must be preserved for two years. Manufacturers, wholesalers and pharmacists are also required to keep every requisition, order and private prescription against which a controlled drug is supplied for two years. In addition, certain other persons are required to keep for two years invoices or similar records relating to all Schedule 3 and 5 drugs that are obtained and supplied.

1.17 At present, the original register, requisition, order and private prescription must be preserved. The 2001 Regulations permit the keeping of copies of invoices, but it is not entirely explicit that they allow such records to be held on computer, or archived by any other means (e.g. microfiche or disk).

Objective

1.18 In order to clarify the situation, the proposal is to amend the requirements relating to the preservation of requisitions, orders and private prescriptions to allow the information they contain to be preserved in original form, or as a copy on computer. In addition, the proposal is to amend the provisions governing the preservation of invoices to allow the information they contain to be held electronically.

Options

1.19 Two options have been identified:

Option 1 – do nothing.

Option 2 – amend the law as proposed to allow registers, requisitions, orders, private prescriptions and invoices to be preserved in original form or as a copy on computer.

Economic and Social Benefits

1.20 Option 1 – None. The position will remain that only the original copy of the relevant records should be preserved. It will also remain unclear whether copies of invoices could be preserved in electronic form.

1.21 Option 2 – The proposal to allow these records to be preserved on computer would benefit all the record holders who have computer facilities, as it would give them the choice of saving storage space.

**Proposal 2- Extend the provisions relating to Extended Formulary Nurse Prescribers**

Issue

2.1 The purpose of this measure is to extend the range of controlled drugs that an Extended Formulary Nurse Prescriber (EFNP) can prescribe for certain named medical conditions. Extended Formulary Nurse Prescribing

was introduced in April 2002 and allowed EFNPs to prescribe from a range of medicines for a range of conditions. Following approval by the Advisory Council on the Misuse of Drugs (ACMD) in November 2001, the Extended Formulary Nurse Prescriber (EFNP)) was expanded in January 2004 to include 6 controlled drugs (CDs). These include schedule 4 CDs midazolam, diazepam and lorazepam (to be used for palliative care only) and schedule 5 CDs codeine, co-phenotrope, dihydrocodeine tartrate (to be used outside of palliative care).

2.2 A meeting of representatives from the ACMD and CSM was held in October 2004. The outcome of the meeting was the provisional agreement to include 5 CDs to the EFNP and a preliminary approval to include a further 2 for acute alcohol withdrawal, subject to the final recommendation of the CSM. This agreement was subject to the concerns raised by the ACMD's Shipman Committee around the need to strengthen arrangements around the management of CDs, as well as training and education issues, in order to minimise the potential for diversion.

2.3 The ACMD's Shipman Committee subsequently endorsed the inclusion of the additional 7 CDs. Whilst certain concerns remained, the Committee was (1) reassured by various aspects of the implementation of the 'Response to The Shipman Inquiry's Fourth Report' and (2) concerned that further delay by ACMD providing a full recommendation could compromise patient care. The ACMD's Technical Committee noted the Shipman Committee's concerns and endorsed the recommendation which subsequently accepted by the whole ACMD.

Objective

2.4 That the following drugs controlled under the Misuse of Drugs Act 1971 are added to the EFNP which will then allow this particular group of nurses, who all receive specialist training, to prescribe them solely for the medical conditions indicated as follows and for the Misuse of Drugs Regulations to be changed accordingly:

*For pain relief or suspected/myocardial infarcation, and acute pain/severe pain after trauma including post operatively:*

Diamorphine
Morphine

*For Palliative Care:*

Diamorphine
Morphine
Buprenorphine for transdermal use
Fentanyl for transdermal use
Oxycodone

*For acute alcohol withdrawal*

Chlordiazepoxide hydrochloride
Diazepam

Options

2.5 Two options have been identified:

Option 1) Do nothing. A doctor would still have to be present to prescribe the above drugs rather than carrying out other duties.

Option 2) Amend the law to allow Extended Formulary Nurse Prescribers to prescribe an additional 7 controlled drugs for specific medical conditions.

Economic and Social Benefits

2.6 Option 1- None. Not allowing Extended Formulary Nurse Prescribers to have the capacity to prescribe an additional range of controlled drugs in certain settings will continue to restrict their ability to carry out their duties effectively. It will also mean that a doctor would continue to have to present to deal with administration of drugs to patients who have the specific conditions named above. Patients in some cases will be in considerable pain while a doctor is being sought.

2.7 Option 2 - The proposed extension of the Extended Formulary Nurse Prescriber (EFNP) is intended to enhance patient care by enabling nurses to provide timely, safe and efficient access to appropriate medication in a variety of settings. Increasingly, experienced nurses and advanced nurse practitioners are able and often best placed to complete all the components of care within their competence. Nurses are supporting and enabling the planned expansion of many NHS services, helping to reduce waiting times and increase quality, by enabling doctors to concentrate their efforts on more complex prescribing cases. The addition of the specific controlled drugs in question to the EFNP will enable nurse prescribers working in drug abuse teams, palliative care teams, Accident and Emergency, and post-operatively to improve patient care and reduce the overall burden on doctors. The ability to prescribe these drugs will only be extended to about 5,000 nurses out of a total of 440,000. The nurses must first be fully trained and demonstrate their competency.

**Proposal 3 - Adding ascorbic acid to allowable paraphernalia items**

Issue

3.1 The Misuse of Drugs (Amendment) (No.2) Regulation 2003 (SI No: 2003/1653) which came into force on 1 August 2003 amended section 9A of the Misuse of Drugs Act 1971 to give doctors, pharmacists and drug workers the authority to supply certain items of drug injecting articles (known as "paraphernalia") to drug users.

3.2 The SI implemented the change by inserting a new Regulation 6A into the Misuse of Drugs Regulations 2001 and added the following articles to the list of drug injecting equipment that are to be excluded from the prohibition in section 9A of the 1971 Act:

(a) "swabs";
(b) "utensils for the preparation of a controlled drug" (which would include articles such as spoons, bowls, cups, dishes);
(c) "citric acid";
(d) "filters"; and
(e) "ampoules of water for injection".

3.3 The SI also provided that only the following persons could supply the five paraphernalia items:

(i) medical practitioners (e.g. doctors, dentists and vets);
(ii) pharmacists; and
(iii) persons employed or engaged in the lawful provision of drug treatment services (i.e. this should include nurses and employees of needle exchange schemes).

3.4 However, the list of allowable items was not extended to include ascorbic acid. At that time when the Advisory Council on the Misuse of Drugs considered the use of acidifiers (which dilute the drug to make it easier to inject), it focussed its discussion on heroin users and citric acid. It was subsequently discovered that addicts who inject cocaine or crack cocaine tend to use ascorbic acid rather than citric acid.

Objective

3.5 To allow addicts who inject cocaine or crack to use ascorbic acid. By adding ascorbic acid to the current list of legal paraphernalia items used by injecting drug users, this amendment will aid in the reduction of the level of harm (injection related infections such as hepatitis and HIV) that addicts face when choosing an acidifier to use for injecting cocaine or crack and to also allow pharmacists and drug workers in exchange schemes to supply ascorbic acid legally.

Options

3.6 Two options have been identified:

> Option 1) Do nothing. Drug Treatment workers are still unable to legally provide ascorbic acid to drug injecting cocaine users.
>
> Option 2) amend the law to make the supply of ascorbic acid lawful, but only if supplied doctors, pharmacists and drug workers and so reduce the levels of harm and drug related death for injecting cocaine or crack addicts.

Economic and Social Benefits

3.7. Option 1) None. Addicts who inject cocaine/crack cocaine will continue to place themselves at additional of harm by not presenting to treatment centres as they cannot having lawful access to ascorbic acid as allowable drug paraphernlia.

3.8 Option 2) The level of harm will be reduced if health professionals and drug workers in needle exchange programmes are able to provide ascorbic acid to their clients.

**Proposal 4 – Removal from paragraph 2 of Schedule 5 of the reference to 0.1% Cocaine preparation**

Issue

4.1 Cocaine seizures are regularly submitted to the Forensic Science Service by Police and Customs for examination in cases where the intended prosecution is for possession or importation. For example, in 2003, 3,896 items were submitted for forensic examination where the intended prosecution was for possession. Analysis tests were carried out on 393 to determine purity; 223 of that total for an amount of less than 0.5 grams. In every case, FSS is required to analyse the amount of cocaine in the preparation to determine whether or not the threshold is below or above 0.1%. However, although this analysis is carried out to test the purity of the cocaine to assist the court with sentencing, it is often only requested in order to decide whether or not to proceed with a prosecution. Consequently there is additional and unnecessary analytical work carried out by FSS annually, disproportionate to the cost involved to the Police and Customs. The annual cost is estimated by the Forensic Science service is in the region of £30k per annum. In addition, some cases are contested, and a significant amount of time is lost by analysts having to attend court.

Objective

4.2 The change now planned will result in all cocaine preparations being controlled under Schedule 2 of the 2001 Regulations. The Chief Pharmaceutical Officer has confirmed that cocaine is virtually obsolete as a therapeutic drug. As far as he is aware, there are no commercial or NHS hospital manufactured goods currently available that contain less than 0.2% of cocaine.

Options

4.3 Two options have been identified;

Option 1) Do nothing.

Option 2) Amend the law to remove the reference to 0.1% preparation of cocaine from paragraph 2 of Schedule 5 of the Regulations.

Economic and Social Benefits

4.4 Option 1) None. FSS would continue to waste resources carrying out analysis to test for the purity of minute amounts of cocaine when these resources could be better employed elsewhere.

4.5 Option 2) amending the schedule to remove the reference to a preparation of cocaine remove the costs incurred by the FSS when carrying out tests on any preparation of cocaine. This will save costs of approximately £30,000 per annum to the Police and Customs, to whom these costs are passed on to.

## 5. COMPLIANCE COSTS

**Proposal 1 - Prescriptions for Controlled Drugs**

5.1 This proposal will have a direct effect on medical practitioners (i.e. doctors, dentists and vets) operating in the public and private sectors that issue prescriptions for the relevant controlled drugs. There may be some transitional costs as a result of GPs introducing the software to generate prescriptions, but this is likely to be minimal. The voluntary nature of the change means that there will be no compliance costs. GPs have an option of preparing prescriptions on computer if they have the appropriate facilities.

**Proposal 1B – Registers for Controlled Drugs & Proposal 1C – Other Record Keeping Requirements for Controlled Drugs**

5.2 Proposals B and C will affect:

- licensed pharmaceutical manufacturers and wholesalers;
- pharmacists and persons operating retail pharmacy businesses;
- doctors, dentists and vets;
- persons in charge of hospitals and nursing homes which are publicly funded or run by charities and voluntary organisations;
- persons in charge of merchant ships and offshore installations;
- persons in charge of authorised laboratories that conduct scientific research;
- public analysts, sampling officers, persons authorised by the Royal Pharmaceutical Society, and authorised persons engaged in testing the quality of drugs.

5.3 There will be no compliance costs on these persons as the two proposals will just give them an option to keep the relevant records on computer if they have the appropriate facilities. However, pharmacists may find additional costs placed on them for the necessary software for CDRs, although hardware costs will be claimed back from DH when connected for ETP provided an ETP credited system is used.

**Proposal 2 – Extending the provisions for Extended Formulary Nurse Prescribers**

5.4 This proposal will effect:

- Extended Formulary Nurse Prescribers

5.5 There will be additional requirement for clear lines of accountability and communication, a system of professional regulation and adequate and appropriate training to ensure that the EFNPs are able to carry out this additional competency safely and securely. It is considered that compliance costs to allow for this measure in the form of additional training will be relatively low, as there are only currently about 5,000 EFNPs.

**Proposal 3 – Addition of Ascorbic Acid to allowable list of paraphernalia**

5.6 The proposal will affect:

- Medical practitioners (e.g. doctors, dentists and vets)
- Pharmacists
- Persons employed in the lawful provision of drug treatment services

(this will include nurses and employees of needle exchange schemes)

5.7 There will be no compliance costs placed on these persons as this proposal will just provide an additional means of help to their clients.

**Proposal 4 - Removal of reference to 0.1% cocaine preparation**

5.8 This proposal will affect:

- The Police and Customs
- The Forensic Science Service
- The Courts

5.9 There will no compliance costs placed on these persons as the analytical procedures of analysis and determination will have been removed completely from the legal process.

## 6. ENVIRONMENTAL IMPACT

The benefits of these measures are predominantly economic and social which are set out in section 1. None of the measures detailed above will have any measurable impact on the environment.

## 7. RACIAL EQUALITY ASSESSMENT

None of the measures detailed in the RIA will have any disproportionate impact on any particular racial group.

## 8. CONSULTATION WITH SMALL BUSINESS

None of the proposals will have any significant depreciable level of impact on small business. There is a company who already produce sterile sachets of ascorbic acid specifically for drug injectors, but distribution and supply is currently illegal as they are not covered by regulation 6A. There will be an opportunity for this company to benefit from the proposal to add ascorbic acid to the list of allowable paraphernalia items.

## 9. COMPETITION ASSESSMENT

The proposals outlined above would have no adverse effects on competition within the market, as they do not introduce any incentives or disincentives to competition.

## 10. RESULTS OF CONSULTATION

The section dealing with computer prescriptions was issued as a formal public consultation in May 2003. The RIA circulated for comments with the consultation to the various interested organisations on those proposals did not reveal any unfavourable responses or any concerns over increased costs.

## 11. RECOMMENDATION

The option to amend the law under these proposals is recommended as it will provide the following benefits:

a) provide greater security and reduced costs in time and money to GPs, dentists, vets and Pharmacists with the introduction of computerised prescriptions and provide increased safety to patients (the economic benefits have been estimated at between £2.12M and £4.24M);

b) Allow EFNPs will enable nurse prescribers working in drug abuse teams, palliative care teams, Accident and Emergency, and post-operatively to improve patient care;

c) By adding ascorbic acid to the current list of legal paraphernalia items used by injecting drug users will aid in the reduction of the level of harm (injection related infections such as hepatitis and HIV) that addicts face when choosing an acidifier to use for injecting cocaine or crack and to also allow pharmacists and drug workers in exchange schemes to supply ascorbic acid legally;

d) save disproportionate time to the Forensic Science Service annually by eliminating the need for testing of preparations containing minimal amounts

of cocaine and allow the Police and Customs to make financial savings amounting to approximately £30,000.

## 12. ENFORCEMENT, SANCTIONS, MONITORING & REVIEW

Home Office Drugs Inspectors, police chemist inspection officers and authorised personnel from the Royal Pharmaceutical Society of Great Britain and the Medicines and Healthcare products Regulatory Agency are responsible for enforcing the relevant provisions of the 2001 Regulations The Home Office will monitor the impact of the changes.

## 13. DECLARATION

*I have read the Regulatory Impact Assessment and I am satisfied that the benefits justify the costs.*

*Signed……Paul Goggins……*

*Date* *12th October 2005*

PAUL GOGGINS
Parliamentary Under-Secretary of State
Home Office

**ANNEX A**

## REQUIREMENTS WHICH ATTACH TO THE SCHEDULES OF THE MISUSE OF DRUGS REGULATIONS 2001

**Schedule 1** - covers drugs such as ecstasy, LSD and cannabis that have no currently recognised medicinal uses. For this reason, they may not be prescribed by doctors and may only be possessed under Home Office licence for research and other special purposes. Persons such as police constables and customs officers are authorised by the 2001 Regulations to possess Schedule 1 drugs. Other persons require production, supply or possession licences which, as indicated above, are only granted for research or other special purposes. Licences are also required for import and export. In addition, Regulations 14 (documentation), 18 (marking of containers), 19, 20 (register-keeping requirements), 23 (preservation of records), 26 (furnishing of information) and 27 (destruction) apply. Schedule 1 drugs are subject to the statutory safe custody requirements; and researchers licensed to possess Schedule 1 drugs are required to keep them in a complying controlled drug (CD) cabinet.

**Schedule 2** - includes cocaine, diamorphine (medicinal heroin), morphine, methadone. Schedule 2 drugs are also subject to the additional prescription requirements of Regulation 15; amongst other things, prescriptions must be handwritten by doctors. Regulations 14 (documentation), 16 (supply on prescription), 18 (marking of containers), 19, 20, 21, 23 (keeping and preservation of registers), 26 (furnishing of information) and 27 (destruction) also apply to Schedule 2 drugs. Most Schedule 2 drugs are also subject to the statutory safe custody requirements.

**Schedule 3** - includes certain barbiturates, buprenorphine, temazepam and funitrazepam. Certain health professionals e.g. doctors and pharmacists are authorised by the Regulations to produce, supply or possess Schedule 3 drugs. In other cases an appropriate written authority will be required. Licences are also required for import and export. The prescription writing (including handwriting) requirements apply to Schedule 3 drugs. In addition, Regulations 14 (documentation), 16 (supply on prescription) and, 18 (marking of containers) apply. No register need be kept but Schedule 3 drugs are subject to the requirements of Regulations 22, 23, 24 (keeping and preservation of records). Regulations 26 (furnishing of information) and 27 (destruction - producers and holders of written authorities to supply only) also apply to Schedule 3 drugs. In addition, some Schedule 3 drugs are subject to the statutory safe custody requirements.

**Schedule 4 Part I** - includes 33 benzodiazepines (eg diazepam, lorazepam and nitrazepam) and pemoline. Persons already authorised by the Regulations (eg doctors and pharmacists) or by a written Home Office authority to produce, supply or possess Schedule 4 Part I drugs will automatically be so authorised in respect of GHB and zolpidem. In other cases an appropriate written Home Office authority will be

required. Licences are also required for imports and exports of Schedule 4 Part I drugs. The Regulation 15 prescription writing (including handwriting) requirements do not apply to Schedule 4 Part I drugs. Regulations 22, 23 (keeping and preservation of records), 26 (furnishing of information) and 27 (destruction - holders of written authorities to produce only) also apply to Schedule 4 Part I drugs. Schedule 4 Part I drugs are not subject to the safe custody requirements.

**Schedule 4 Part II** - includes 54 anabolic substances e.g. nandrolone and testosterone. Persons already authorised by the 2001 Regulations (e.g. doctors and pharmacists) or by a written Home Office authority to produce, supply or possess* Schedule 4 Part II drugs will automatically be authorised in respect of these anabolic steroids. In other cases an appropriate written Home Office authority will be required. [* NB Possession licences are not required if the substances are in medicinal product form.]

Import and export licences are required for the trade in Schedule 4 Part II substances. The Regulation 15 prescription writing (including handwriting) requirements do not apply to Schedule 4 Part II drugs. Regulations 22, 23 (keeping and preservation of records), 26 (furnishing of information) and 27 (destruction - holders of written authorities to produce only) also apply to Schedule 4 Part II drugs. Schedule 4 Part II drugs are not subject to the statutory safe custody requirements.

**Schedule 5** - covers weak preparations of certain controlled drugs e.g. codeine, kaolin and morph which are not liable to cause significant harm if misused. It is the lightest level of control. Certain health professionals e.g. doctors and pharmacists are authorised by the Regulations to produce, supply or possess Schedule 5 drugs. In other cases a written authority to produce or supply is required. Schedule 5 drugs are exempted from import, export and possession controls. They do not necessarily require a prescription; the prescription handwriting requirements do not apply to Schedule 5 drugs. Finally, they are subject to some record-keeping requirements.