

# SI 2001/3998 (Amended)

## The Misuse of Drugs Regulations 2001

### Statutory Instrument 2001 No. 3998

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#### STATUTORY INSTRUMENTS

2001 No. 3998

#### DANGEROUS DRUGS

#### The Misuse of Drugs Regulations 2001

Made	13th December 2001
Laid before Parliament	14th December 2001
Coming into force	1st February 2002

#### ARRANGEMENT OF REGULATIONS

Citation and commencement .....	2
Interpretation.....	2
Specification of controlled drugs for purposes of Regulations.....	6
Exceptions for drugs in Schedules 4 and 5 and poppy-straw.....	6
Exceptions for drugs in Schedule 1 .....	7
Licences to produce etc. controlled drugs .....	7
General authority to supply and possess.....	7
Supply of articles for administering or preparing controlled drugs .....	8
Administration of drugs in Schedules 2, 3, 4 and 5 .....	9
Production and supply of drugs in Schedules 2 and 5.....	10
Production and supply of drugs in Schedules 3 and 4.....	12
Possession of drugs in Schedules 2, 3 and 4.....	14
Exemption for midwives.....	16
Cultivation under licence of cannabis plant .....	17
Approval of premises for cannabis smoking for research purposes .....	17
Documents to be obtained by supplier of controlled drugs.....	17
Form of prescriptions .....	19

## SI 2001/3998 (Amended)

Provisions as to supply on prescription .....	20
Exemption for certain prescriptions .....	22
Marking of bottles and other containers.....	22
Record-keeping requirements in respect of drugs in Schedules 1 and 2 .....	23
Requirements as to registers.....	24
Record-keeping requirements in respect of drugs in Schedule 2 in particular cases .....	25
Record-keeping requirements in respect of drugs Schedules 3 and 4 .....	25
Preservation of registers, books and other documents .....	25
Preservation of records relating to drugs in Schedules 3 and 5 .....	26
Exempt products.....	26
Furnishing of information with respect to controlled drugs .....	26
Destruction of controlled drugs.....	27
Revocations.....	27
SCHEDULE 1 Regulation 3 CONTROLLED DRUGS SUBJECT TO THE REQUIREMENTS OF REGULATIONS 14, 15, 16, 18, 19, 20, 23, 26 AND 27 .....	29
SCHEDULE 2 Regulation 3 CONTROLLED DRUGS SUBJECT TO THE REQUIREMENTS OF REGULATIONS 14, 15, 16, 18, 19, 20, 21, 23, 26 AND 27 .....	32
SCHEDULE 3 Regulation 3 CONTROLLED DRUGS SUBJECT TO THE REQUIREMENTS OF REGULATIONS 14, 15 (EXCEPT TEMAZEPAM), 16, 18, 22, 23, 24, 26 AND 27 .....	34
SCHEDULE 4 Regulation 3.....	34
PART I - CONTROLLED DRUGS SUBJECT TO THE REQUIREMENTS OF REGULATIONS 22, 23, 26 AND 27 .....	34
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 .....	36
SCHEDULE 5 Regulation 3 CONTROLLED DRUGS EXCEPTED FROM THE PROHIBITION ON IMPORTATION, EXPORTATION AND POSSESSION AND SUBJECT TO THE REQUIREMENTS OF REGULATIONS 24 AND 26 .....	37
<del>SCHEDULE 6 Regulation 19 FORM OF REGISTER .....</del>	<del>39</del>
<del>(Schedule 6 deleted with effect from 1/2/2008) .....</del>	<del>39</del>
<del>PART I - Entries to be made in case of obtaining.....</del>	<del>39</del>
<del>PART II - Entries to be made in case of supply.....</del>	<del>39</del>
SCHEDULE 7 Regulation 28 REGULATIONS REVOKED.....	40
SCHEDULE 8 Regulations 8(8) and 9(8) .....	40

The Secretary of State, in exercise of the powers conferred on him by sections 7, 10, 22 and 31 of the Misuse of Drugs Act 1971<sup>[1]</sup>, after consultation with the Advisory Council on the Misuse of Drugs in accordance with section 31(3) of that Act, hereby makes the following Regulations:

### Citation and commencement

1. These Regulations may be cited as the Misuse of Drugs Regulations 2001 and shall come into force on 1st February 2002.

### Interpretation

2. - (1) In these Regulations, unless the context otherwise requires -

"the Act" means the Misuse of Drugs Act 1971;

"accountable officer" has the same meaning as in the Health Act 2006;<sup>1</sup>

"authorised as a member of a group" means authorised by virtue of being a member of a class as respects which the Secretary of State has granted an authority under and for the purposes of regulation 8(3), 9(3) or 10(3) which is in force, and "his group authority", in relation to a person who is a member of such a class, means the authority so granted to that class;

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<sup>1</sup> Inserted by SI 2007/2154

## SI 2001/3998 (Amended)

“care home” in relation to—

- (a) England and Wales has the same meaning as in the Care Standards Act 2000; and
- (b) Scotland means the accommodation provided by a care home service;<sup>2</sup>

“care home service” has the same meaning as in the Regulation of Care (Scotland) Act 2001;<sup>3</sup>

“clinical management plan” has the same meaning as in the Prescription Only Medicines (Human Use) Order 1997;<sup>4</sup>

“the Common Services Agency for the health service” means the body established under section 10 of the National Health Service (Scotland) Act 1978;<sup>5</sup>

~~“document” has the same meaning as in Part I of the Civil Evidence Act 1968[2]~~ means anything in which information of any description is recorded (within the meaning of the Civil Evidence Act 1995.<sup>6</sup>

“equivalent body” means a Local Health Board in Wales, a Health Board in Scotland or the Northern Ireland Central Services Agency for the Health and Social Services in Northern Ireland;<sup>7</sup>

“exempt product” means a preparation or other product consisting of one or more component parts, any of which contains a controlled drug, where –

- (a) the preparation or other product is not designed for administration of the controlled drug to a human being or animal;
- (b) the controlled drug in any component part is packaged in such a form, or in combination with other active or inert substances in such a manner, that it cannot be recovered by readily applicable means or in a yield which constitutes a risk to health; and
- (c) no one component part of the product or preparation contains more than one milligram of the controlled drug or one microgram in the case of lysergide or any other N-alkyl derivative of lysergamide;

“Health Board” means a board constituted under section 2 of the National Health Service (Scotland) Act 1978;<sup>8</sup>

~~“extended formulary nurse prescriber” has the same meaning as in the Prescription Only Medicines (Human Use) Order 1997, and such a person may only prescribe—~~

- ~~(a) diazepam, lorazepam or midazolam for use in palliative care;~~
- ~~(b) codeine phosphate, dihydrocodeine tartrate or co-phenotrope;<sup>9</sup>~~

~~“extended formulary nurse prescriber” has the same meaning as in the Prescription Only Medicines (Human Use) Order 1997, and such a person may only prescribe controlled drugs in accordance with regulation 6B;<sup>10</sup>~~

“health prescription” means a prescription issued by a doctor or a dentist under the National Health Service Act 1977[3], the National Health Service (Scotland) Act 1978[4], the Health and Personal Social Services (Northern Ireland) Order 1972[5] or the National Health Service (Isle of Man) Acts 1948 to 1979 (Acts of Tynwald) or upon a form issued by a local authority for use in connection with the health service of that authority;

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<sup>2</sup> Inserted by SI 2007/2154

<sup>3</sup> Inserted by SI 2007/2154

<sup>4</sup> Inserted by SI 2005/271

<sup>5</sup> Inserted by SI 2006/1450

<sup>6</sup> Amended by SI 2003/1653

<sup>7</sup> Inserted by SI 2006/1450

<sup>8</sup> Inserted by SI 2006/1450

<sup>9</sup> Inserted by SI 2003/2429, Deleted by SI 2005/2864

<sup>10</sup> Inserted by SI 2005/2864, Deleted by SI 2006/986

## SI 2001/3998 (Amended)

"installation manager" and "offshore installation" have the same meanings as in the Mineral Workings (Offshore Installations) Act 1971[6];

"Local Health Board" means a Local Health Board established in accordance with section 16BA of the National Health Service Act 1977;<sup>11</sup>

"master" and "seamen" have the same meanings as in the Merchant Shipping Act 1995[7];

"medicinal product" has the same meaning as in the Medicines Act 1968[8];

"NHS Business Services Authority" means the special health authority established under Article 2 of the NHS Business Services Authority (Awdurdod Gwasanaethau Busnes y GIG) (Establishment and Constitution) Order 2005;<sup>12</sup>

"the Northern Ireland Central Services Agency for the Health and Social Services" means the body established under Article 26 of the Health and Personal Social Services (Northern Ireland) Order 1972;<sup>13</sup>

"nurse independent prescriber" has the same meaning as in the Prescription Only Medicines (Human Use) Order 1997, and such a person may only prescribe controlled drugs in accordance with regulation 6B;<sup>14</sup>

"officer of customs and excise" means an officer within the meaning of the Customs and Excise Management Act 1979[9];

"operating department practitioner" means a person who is registered under the Health Professions Order 2001 as an operating department practitioner;<sup>15</sup>

"patient group direction" has the same meaning as in the Prescription Only Medicines (Human Use) Order 1997;<sup>16</sup>

"pharmacist" has the same meaning as in the Medicines Act 1968;<sup>17</sup>

"prescriber identification number" means the number recorded against a person's name by the relevant National Health Service agency for the purposes of that person's private prescribing;<sup>18</sup>

"prescription" means a prescription issued by a doctor for the medical treatment of a single individual, by ~~an extended formulary~~ a nurse independent prescriber<sup>19</sup> for the medical treatment of a single individual, by a supplementary prescriber for the medical treatment of a single individual<sup>20</sup>, by a dentist for the dental treatment of a single individual or by a veterinary surgeon or veterinary practitioner for the purposes of animal treatment;<sup>21</sup>

"Primary Care Trust" means a Primary Care Trust established under section 16A of the National Health Service Act 1977;<sup>22</sup>

"private prescribing" means issuing prescriptions other than health prescriptions or veterinary prescriptions, ~~where the definition of "prescription" has effect as if the words "or by a veterinary surgeon or veterinary practitioner for the purposes of animal treatment" were omitted;~~<sup>23</sup>

"professional registration number" means the number recorded against a person's name in the register of any body that licenses or regulates any profession of which that person is a member;<sup>24</sup>

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<sup>11</sup> Inserted by SI 2006/1450

<sup>12</sup> Inserted by SI 2006/1450

<sup>13</sup> Inserted by SI 2006/1450

<sup>14</sup> Inserted by SI 2006/986

<sup>15</sup> Inserted by SI 2007/2154

<sup>16</sup> Inserted by SI 2003/2429

<sup>17</sup> Inserted by SI 2006/1450

<sup>18</sup> Inserted by SI 2006/1450

<sup>19</sup> Amended by SI 2006/986

<sup>20</sup> Inserted by SI 2005/271

<sup>21</sup> Amended by SI 2003/2429

<sup>22</sup> Inserted by SI 2006/1450

<sup>23</sup> Inserted by SI 2006/1450, Amended by SI 2006/2178

<sup>24</sup> Inserted by SI 2006/1450

## SI 2001/3998 (Amended)

“professional register” means the register maintained by the Nursing and Midwifery Council under article 5 of the Nursing and Midwifery Order 2001;<sup>25</sup>

~~“register” means a bound book and does not include any form of loose leaf register or card index;~~<sup>26</sup>

“register” means either a bound book, which does not include any form of loose leaf register or card index, or a computerised system which is in accordance with best practice guidance endorsed by the Secretary of State under section 2 of the National Health Service Act 1977;<sup>27</sup>

“registered chiropodist” has the same meaning as in the Prescriptions Only Medicines (Human Use) Order 1997;<sup>28</sup>

~~“registered health visitor” means a person who is registered in the professional register by virtue of qualifications in relation to health visiting and the professional register is the register maintained by the Nursing and Midwifery Council pursuant to paragraph 10 of Schedule 2 to the Nursing and Midwifery Order 2001;~~<sup>29</sup>

“registered midwife” has the same meaning as in the Prescription Only Medicines (Human Use) Order 1997;<sup>30</sup>

“registered nurse” has the same meaning as in the Prescription Only Medicines (Human Use) Order 1997;<sup>31</sup>

“registered occupational therapist” has the same meaning as in the Prescription Only Medicines (Human Use) Order 1997;<sup>32</sup>

“registered optometrist ~~ophthalmic optician~~” has the same meaning as in the Prescription Only Medicines (Human Use) Order 1997;<sup>33</sup>

“registered orthoptist” has the same meaning as in the Prescription Only Medicines (Human Use) Order 1997;<sup>34</sup>

“registered orthotist and prosthetist” has the same meaning as in the Prescription Only Medicines (Human Use) Order 1997;<sup>35</sup>

“registered paramedic” has the same meaning as in the Prescription Only Medicines (Human Use) Order 1997;<sup>36</sup>

“registered pharmacy” has the same meaning as in the Medicines Act 1968;

“registered physiotherapist” has the same meaning as in the Prescription Only Medicines (Human Use) Order 1997;<sup>37</sup>

“registered radiographer” has the same meaning as in the Prescription Only Medicines (Human Use) Order 1997;<sup>38</sup>

“relevant National Health Service agency” means, for England and Wales, the NHS Business Services Authority; for Scotland, the Common Services Agency for the health service; and for Northern Ireland, the Northern Ireland Central Services Agency for the Health and Social Services;<sup>39</sup>

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<sup>25</sup> Inserted by SI 2004/1771

<sup>26</sup> Deleted by SI 2005/2864

<sup>27</sup> Inserted by SI 2005/2864

<sup>28</sup> Inserted by SI 2007/2154

<sup>29</sup> Inserted by SI 2003/2429, Deleted by SI 2004/1771

<sup>30</sup> Inserted by SI 2003/2429

<sup>31</sup> Inserted by SI 2003/2429

<sup>32</sup> Inserted by SI 2006/1450

<sup>33</sup> Inserted by SI 2003/2429, Amended by SI 2007/2154

<sup>34</sup> Inserted by SI 2007/2154

<sup>35</sup> Inserted by SI 2006/1450

<sup>36</sup> Inserted by SI 2007/2154

<sup>37</sup> Inserted by SI 2007/2154

<sup>38</sup> Inserted by SI 2007/2154

<sup>39</sup> Inserted by SI 2006/1450

## SI 2001/3998 (Amended)

"retail dealer" means a person lawfully conducting a retail pharmacy business or a pharmacist engaged in supplying drugs to the public at a health centre within the meaning of the Medicines Act 1968;

~~"sister or acting sister" includes any male nurse occupying a similar position;~~<sup>40</sup>

"specialist community public health nurse" means a registered nurse or midwife who is also registered in the Specialist Community Public Health Nurses' Part of the professional register and against whose name in that Part of the register there is an annotation that she has a qualification in health visiting;<sup>41</sup>

~~"state registered chiropract" has the same meaning as in the Prescription Only Medicines (Human Use) Order 1997;~~<sup>42</sup>

~~"state registered paramedic" has the same meaning as in the Prescription Only Medicines (Human Use) Order 1997;~~<sup>43</sup>

"supplementary prescriber" has the same meaning as in the Prescription Only Medicines (Human Use) Order 1997;<sup>44</sup>

"veterinary prescription" means a prescription issued by a veterinary surgeon or veterinary practitioner for the purposes of animal treatment;<sup>45</sup>

"wholesale dealer" means a person who carries on the business of selling drugs to persons who buy to sell again.

(2) In these Regulations any reference to a regulation or schedule shall be construed as a reference to a regulation contained in these Regulations or, as the case may be, to a schedule to these Regulations, and any reference in a regulation or schedule to a paragraph shall be construed as a reference to a paragraph of that regulation or schedule.

(3) Nothing in these Regulations shall be construed as derogating from any power or immunity of the Crown, its servants or agents.

### Specification of controlled drugs for purposes of Regulations

3. Schedules 1 to 5 shall have effect for the purpose of specifying the controlled drugs to which certain provisions of these Regulations apply.

### Exceptions for drugs in Schedules 4 and 5 and poppy-straw

4. - (1) Section 3(1) of the Act (which prohibits the importation and exportation of controlled drugs) shall not have effect in relation to the drugs specified in Schedule 5.

(2) The application of section 3(1) of the Act, in so far as it creates an offence, and the application of sections 50(1) to (4), 68(2) and (3) or 170 of the Customs and Excise Management Act 1979, in so far as they apply in relation to a prohibition or restriction on importation or exportation having effect by virtue of section 3 of the Act, are hereby excluded in the case of importation or exportation by any person for administration to himself of any drug specified in Part II of Schedule 4 which is contained in a medicinal product.

(3) Section 5(1) of the Act (which prohibits the possession of controlled drugs) shall not have effect in relation to –

(a) any drug specified in Part II of Schedule 4 which is contained in a medicinal product;

(b) the drugs specified in Schedule 5.

(4) Sections 4(1) (which prohibits the production and supply of controlled drugs) and 5(1) of the Act shall not have effect in relation to poppy-straw.

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<sup>40</sup> Deleted by SI 2007/2154

<sup>41</sup> Inserted by SI 2004/1771

<sup>42</sup> Inserted by SI 2003/2429, Deleted by SI 2007/2154

<sup>43</sup> Inserted by SI 2003/2429, Deleted by SI 2007/2154

<sup>44</sup> Inserted by SI 2005/271

<sup>45</sup> Inserted by SI 2006/2178

## SI 2001/3998 (Amended)

(5) Sections 3(1), 4(1) and 5(1) of the Act shall not have effect in relation to any exempt product.

### Exceptions for drugs in Schedule 1

4A. - (1) Section 5(1) of the Act (which prohibits the possession of controlled drugs) shall not have effect in relation to a fungus (of any kind) which contains psilocin or an ester of psilocin(c) where that fungus—

(a) is growing uncultivated;

(b) is picked by a person already in lawful possession of it for the purpose of delivering it as soon as is reasonably practicable into the custody of a person lawfully entitled to take custody of it and it remains in that person's possession for and in accordance with that purpose;

(c) is picked for either of the purposes specified in paragraph (2) and is held for and in accordance with the purpose specified in paragraph (2)(b), either by the person who picked it or by another person; or

(d) is picked for the purpose specified in paragraph (2)(b) and is held for and in accordance with the purpose in paragraph (2)(a), either by the person who picked it or by another person.

(2) The purposes specified for the purposes of this paragraph are—

(a) the purpose of delivering the fungus as soon as is reasonably practicable into the custody of a person lawfully entitled to take custody of it; and

(b) the purpose of destroying the fungus as soon as is reasonably practicable.<sup>46</sup>

### 4B<sup>47</sup> Exceptions for gamma-butyrolactone and 1,4-butanediol

(1) Gamma-butyrolactone and 1,4-butanediol are excepted from sections 3(1) (import and export), 4(1) (production and supply) and 5(1) (possession) of the Act save where a person imports, exports, produces, supplies or offers to supply either substance, or has either substance in his possession, knowing or believing that it will be used for the purpose of human ingestion whether by himself or another person other than as a flavouring in food.

(2) In this regulation references to gamma-butyrolactone and 1,4-butanediol include—

(a) any stereoisomeric form of gamma-butyrolactone or 1,4-butanediol;

(b) any salt of gamma-butyrolactone, 1,4-butanediol or of a substance specified in sub-paragraph (a) of this paragraph; and

(c) any preparation or other product containing gamma-butyrolactone, 1,4-butanediol or a substance specified in sub-paragraph (a) or (b) of this paragraph

### Licences to produce etc. controlled drugs

5. Where any person is authorised by a licence of the Secretary of State issued under this regulation and for the time being in force to produce, supply, offer to supply or have in his possession any controlled drug, it shall not by virtue of section 4(1) or 5(1) of the Act be unlawful for that person to produce, supply, offer to supply or have in his possession that drug in accordance with the terms of the licence and in compliance with any conditions attached to the licence.

### General authority to supply and possess

6. - (1) Notwithstanding the provisions of section 4(1)(b) of the Act, any person who is lawfully in possession of a controlled drug may supply that drug to the person from whom he obtained it.

(2) Notwithstanding the provisions of section 4(1)(b) of the Act, any person who has in his possession a drug specified in Schedule 2, 3, 4 or 5 which has been supplied by or on the prescription of a practitioner, ~~an extended formulary nurse prescriber,~~<sup>48</sup> a registered nurse, a supplementary prescriber<sup>49</sup> or a person specified in Schedule 8 for the treatment of that person, or of a person whom he represents, may supply that drug to any doctor, dentist or pharmacist for the purpose of destruction.<sup>50</sup>

<sup>46</sup> Inserted by SI 2005/1653

<sup>47</sup> Inserted by SI 2009/3136

<sup>48</sup> Deleted by SI 2004/1771

<sup>49</sup> Inserted by 2005/271

<sup>50</sup> Amended by SI 2003/2429

## SI 2001/3998 (Amended)

- (3) Notwithstanding the provisions of section 4(1)(b) of the Act, any person who is lawfully in possession of a drug specified in Schedule 2, 3, 4 or 5 which has been supplied by or on the prescription of a veterinary practitioner or veterinary surgeon for the treatment of animals may supply that drug to any veterinary practitioner, veterinary surgeon or pharmacist for the purpose of destruction.
- (4) It shall not by virtue of section 4(1)(b) or 5(1) of the Act be unlawful for any person in respect of whom a licence has been granted and is in force under section 16(1) of the Wildlife and Countryside Act 1981[10] to supply, offer to supply or have in his possession any drug specified in Schedule 2 or 3 for the purposes for which that licence was granted.
- (5) Notwithstanding the provisions of section 4(1)(b) of the Act, any of the persons specified in paragraph (7) may supply any controlled drug to any person who may lawfully have that drug in his possession.
- (6) Notwithstanding the provisions of section 5(1) of the Act, any of the persons so specified may have any controlled drug in his possession.
- (7) The persons referred to in paragraphs (5) and (6) are
  - (a) a constable when acting in the course of his duty as such;
  - (b) a person engaged in the business of a carrier when acting in the course of that business;
  - (c) a person engaged in the business of the ~~Post Office~~ a postal operator (within the meaning of the Postal Services Act 2000)<sup>51</sup> when acting in the course of that business;
  - (d) an officer of customs and excise when acting in the course of his duty as such;
  - (e) a person engaged in the work of any laboratory to which the drug has been sent for forensic examination when acting in the course of his duty as a person so engaged;
  - (f) a person engaged in conveying the drug to a person who may lawfully have that drug in his possession.

### Supply of articles for administering or preparing controlled drugs<sup>52</sup>

- 6A.—(1) Notwithstanding the provisions of section 9A(1) and (3) of the Act, any of the persons specified in paragraph (2) may, when acting in their capacity as such, supply or offer to supply the following articles—
- (a) a swab;
  - (b) utensils for the preparation of a controlled drug;
  - (c) citric acid;
  - (d) a filter;
  - (e) ampoules of water for injection, only when supplied or offered for supply in accordance with the Medicines Act 1968 and of any instrument which is in force thereunder;
  - (f) ascorbic acid.<sup>53</sup>
- (2) The persons referred to in paragraph (1) are—
- (a) a practitioner;
  - (b) a pharmacist;
  - (c) a person employed or engaged in the lawful provision of drug treatment services.
  - (d) a supplementary prescriber acting under and in accordance with the terms of a clinical management plan.<sup>54</sup>

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<sup>51</sup> Amended by SI 2003/1653

<sup>52</sup> Inserted by SI 2003/1653

<sup>53</sup> Inserted by 2005/2864

<sup>54</sup> Inserted by SI 2005/271



## SI 2001/3998 (Amended)

### Authority for ~~Extended Formulary Nurse Independent Prescribers~~<sup>55</sup> to prescribe

6B. ~~An extended formulary nurse prescriber~~ A nurse independent prescriber<sup>56</sup> may only prescribe—

- (a) diamorphine, ~~diazepam, lorazepam, midazolam~~<sup>57</sup>, morphine or oxycodone for use in palliative care;
- (b) buprenorphine or fentanyl for transdermal use in palliative care;
- (c) diamorphine or morphine 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;
- (d) chlordiazepoxide hydrochloride or diazepam for treatment of initial or acute withdrawal symptoms caused by the withdrawal of alcohol from persons habituated to it;
- (e) codeine phosphate, dihydrocodeine tartrate or co-phenotrope<sup>58</sup> and
- (f) diazepam, lorazepam or midazolam for use in palliative care or treatment of tonic-clonic seizures.<sup>59</sup>

### Administration of drugs in Schedules 2, 3, 4 and 5

7. - (1) Any person may administer to another any drug specified in Schedule 5.

(2) A doctor or dentist may administer to a patient any drug specified in Schedule 2, 3 or 4.

(3) Any person other than a doctor or dentist may administer to a patient, in accordance with the directions of a doctor or dentist, any drug specified in Schedule 2, 3 or 4.

~~(4) Notwithstanding the provisions of paragraph (3), an extended formulary nurse prescriber may administer to a patient, without the directions of a doctor or dentist, diazepam, lorazepam and midazolam for use in palliative care.~~<sup>60</sup>

(4) Notwithstanding the provisions of paragraph (3), ~~an extended formulary nurse prescriber~~ a nurse independent prescriber<sup>61</sup> may administer to a patient, without the directions of a doctor or dentist, any controlled drug which she may prescribe under regulation 6B provided it is administered for a purpose for which it may be prescribed under that regulation.<sup>62</sup>

~~(5) Notwithstanding the provisions of paragraph (3), any person may administer to a patient, in accordance with the directions of an extended formulary nurse prescriber, diazepam, lorazepam and midazolam for use in palliative care.~~<sup>63</sup>

(5) Notwithstanding the provisions of paragraph (3), any person may administer to a patient in accordance with the specific directions of ~~an extended formulary nurse prescriber~~ a nurse independent prescriber<sup>64</sup> any controlled drug which ~~the extended formulary nurse prescriber~~ the nurse independent prescriber<sup>65</sup> may prescribe under regulation 6B provided it is administered for a purpose for which it may be prescribed under that regulation.<sup>66</sup>

(6) Notwithstanding the provisions of paragraph (3), a supplementary prescriber acting under and in accordance with the terms of a clinical management plan may administer to a patient, without the directions of a doctor or dentist, any drug specified in Schedule 2, 3 or 4.<sup>67</sup>

(7) Notwithstanding the provisions of paragraph (3), any person may administer to a patient, in accordance with the directions of a supplementary prescriber acting under and in accordance with the terms of a clinical management plan, any drug specified in Schedule 2, 3 or 4.<sup>68</sup>

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<sup>55</sup> Amended by SI 2006/986

<sup>56</sup> Amended by SI 2006/986

<sup>57</sup> Deleted by SI 2006/986

<sup>58</sup> Inserted by SI 2005/2864

<sup>59</sup> Inserted by SI 2006/986

<sup>60</sup> Inserted by SI 2003/2429, Deleted by SI 2005/2864

<sup>61</sup> Amended by SI 2006/986

<sup>62</sup> Inserted by SI 2005/2864

<sup>63</sup> Inserted by SI 2003/2429, Deleted by SI 2005/2864

<sup>64</sup> Amended by SI 2006/986

<sup>65</sup> Amended by SI 2006/986

<sup>66</sup> Inserted by SI 2005/2864

<sup>67</sup> Inserted by 2005/271

## SI 2001/3998 (Amended)

### Production and supply of drugs in Schedules 2 and 5

8. - (1) Notwithstanding the provisions of section 4(1)(a) of the Act –

- (a) a practitioner or pharmacist, acting in his capacity as such, may manufacture or compound any drug specified in Schedule 2 or 5;
- (b) a person lawfully conducting a retail pharmacy business and acting in his capacity as such may, at the registered pharmacy at which he carries on that business, manufacture or compound any drug specified in Schedule 2 or 5.

(2) Notwithstanding the provisions of section 4(1)(b) of the Act, any of the following persons, that is to say –

- (a) a practitioner;
  - (b) a pharmacist;
  - (c) a person lawfully conducting a retail pharmacy business;
  - (d) the person in charge or acting person in charge of a hospital or ~~nursing~~ care home which is wholly or mainly maintained by a public authority out of public funds or by a charity or by voluntary subscriptions;<sup>69</sup>
  - (e) in the case of such a drug supplied to her by a person responsible for the dispensing and supply of medicines at the hospital or ~~nursing~~ care home, the ~~sister or acting sister~~ senior registered nurse or acting senior registered nurse for the time being in charge of a ward, theatre or other department in such a hospital or ~~nursing~~ care home as aforesaid;<sup>70</sup>
  - (ea) in the case of such a drug supplied to him by a person responsible for the dispensing and supply of medicines at a hospital, an operating department practitioner practising in that hospital;<sup>71</sup>
  - (f) a person who is in charge of a laboratory the recognised activities of which consist in, or include, the conduct of scientific education or research and which is attached to a university, university college or such a hospital as aforesaid or to any other institution approved for the purpose under this sub-paragraph by the Secretary of State;
  - (g) a public analyst appointed under section 27 of the Food Safety Act 1990[11];
  - (h) a sampling officer within the meaning of Schedule 3 to the Medicines Act 1968;
  - (i) a person employed or engaged in connection with a scheme for testing the quality or amount of the drugs, preparations and appliances supplied under the National Health Service Act 1977 or the National Health Service (Scotland) Act 1978 and the regulations made thereunder;
  - (j) a person authorised by the Pharmaceutical Society of Great Britain for the purposes of section 108 or 109 of the Medicines Act 1968,
  - (k) a supplementary prescriber acting under and in accordance with the terms of a clinical management plan,<sup>72</sup>
- may, when acting in his capacity as such, supply or offer to supply any drug specified in Schedule 2 or 5 to any person who may lawfully have that drug in his possession, except that nothing in this paragraph authorises –
- (†) the person in charge or acting person in charge of a hospital or ~~nursing~~ care home, having a pharmacist responsible for the dispensing and supply of medicines, to supply or offer to supply any drug;<sup>73</sup>

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<sup>68</sup> Inserted by 2005/271

<sup>69</sup> Amended by SI 2007/2154

<sup>70</sup> Amended by SI 2007/2154

<sup>71</sup> Inserted by SI 2007/2154

<sup>72</sup> Inserted by 2005/271

<sup>73</sup> Amended by SI 2007/2154

## SI 2001/3998 (Amended)

- (ii) ~~sister or acting sister~~ senior registered nurse or acting senior registered nurse for the time being in charge of a ward, theatre or other department to supply any drug otherwise than for administration to a patient in that ward, theatre or department in accordance with the directions of a doctor, ~~or~~ dentist, supplementary prescriber acting under and in accordance with the terms of a clinical management plan or, subject to paragraph (2A), a nurse independent prescriber; or<sup>74</sup>
- (iii) an operating department practitioner to supply any drug otherwise than for administration to a patient in a ward, theatre or other department in accordance with the directions of a doctor, dentist, supplementary prescriber acting under and in accordance with the terms of a clinical management plan or, subject to paragraph (2A), a nurse independent prescriber.<sup>75</sup>
- (2A) The directions given by a nurse independent prescriber referred to in paragraph (2)(ii) and (iii) shall relate only to a controlled drug which she may prescribe under regulation 6B and a purpose for which it may be prescribed under that regulation.<sup>76</sup>
- (3) Notwithstanding the provisions of section 4(1)(b) of the Act, a person who is authorised as a member of a group may, under and in accordance with the terms of his group authority and in compliance with any conditions attached thereto, supply or offer to supply any drug specified in Schedule 2 or 5 to any person who may lawfully have that drug in his possession.
- (4) Notwithstanding the provisions of section 4(1)(b) of the Act, a person who is authorised by a written authority issued by the Secretary of State under and for the purposes of this paragraph and for the time being in force may, at the premises specified in that authority and in compliance with any conditions so specified, supply or offer to supply any drug specified in Schedule 5 to any person who may lawfully have that drug in his possession.
- (5) Notwithstanding the provisions of section 4(1)(b) of the Act –
- (a) the owner of a ship, or the master of a ship which does not carry a doctor among the seamen employed in it; or
- (b) the installation manager of an offshore installation,
- may supply or offer to supply any drug specified in Schedule 2 or 5 –
- (i) for the purpose of compliance with any of the provisions specified in paragraph (6), to any person on that ship or installation;
- (ii) to any person who may lawfully supply that drug to him;
- (iii) to any constable for the purpose of the destruction of that drug.
- (6) The provisions referred to in paragraph (5) are any provision of, or of any instrument which is in force under –
- (a) the Mineral Workings (Offshore Installations) Act 1971;
- (b) the Health and Safety at Work etc. Act 1974[12] or
- (c) the Merchant Shipping Act 1995.
- ~~(7) Notwithstanding the provisions of section 4(1)(b) of the Act, an extended formulary nurse prescriber may, when acting in her capacity as such, supply or offer to supply codeine phosphate, dihydrocodeine tartrate and co-phenotrope, to any person who may lawfully have any of these drugs in his possession.<sup>77</sup>~~
- (7) Notwithstanding the provisions of section 4(1)(b) of the Act, ~~an extended formulary nurse prescriber~~ a nurse independent prescriber<sup>78</sup> may, when acting in her capacity as such, supply or offer to supply—
- (a) codeine phosphate, dihydrocodeine tartrate and co-phenotrope;

<sup>74</sup> Amended by SI 2007/2154

<sup>75</sup> Inserted by SI 2007/2154

<sup>76</sup> Inserted by SI 2007/2154

<sup>77</sup> Inserted by SI 2003/2429, Deleted by SI 2005/2864

<sup>78</sup> Amended by SI 2006/986

## SI 2001/3998 (Amended)

- (b) diamorphine and morphine 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;
- (c) diamorphine, morphine and oxycodone for use in palliative care; and
- (d) fentanyl for transdermal use in palliative care,

to any person who may lawfully have any of these drugs in his possession.<sup>79</sup>

(8) Notwithstanding the provisions of section 4(1)(b) of the Act—

- (a) a registered nurse, when acting in her capacity as such, may supply or offer to supply, under and in accordance with the terms of a patient group direction, diamorphine for the treatment of cardiac pain to a person admitted as a patient to a coronary care unit or an accident and emergency department of a hospital;<sup>80</sup>
- (b) a registered nurse or a person specified in Schedule 8 may, when acting in their capacity as such, supply or offer to supply, under and in accordance with the terms of a patient group direction, any drug specified in Schedule 5 to any person who may lawfully have that drug in his possession.<sup>81</sup>

### Production and supply of drugs in Schedules 3 and 4

9. - (1) Notwithstanding the provisions of section 4(1)(a) of the Act –

- (a) a practitioner or pharmacist, acting in his capacity as such, may manufacture or compound any drug specified in Schedule 3 or 4;
- (b) a person lawfully conducting a retail pharmacy business and acting in his capacity as such may, at the registered pharmacy at which he carries on that business, manufacture or compound any drug specified in Schedule 3 or 4;
- (c) a person who is authorised by a written authority issued by the Secretary of State under and for the purposes of this sub-paragraph and for the time being in force may, at the premises specified in that authority and in compliance with any conditions so specified, produce any drug specified in Schedule 3 or 4.

(2) Notwithstanding the provisions of section 4(1)(b) of the Act, any of the following persons, that is to say –

- (a) a practitioner;
- (b) a pharmacist;
- (c) a person lawfully conducting a retail pharmacy business;
- (d) a person in charge of a laboratory the recognised activities of which consist in, or include, the conduct of scientific education or research;
- (e) a public analyst appointed under section 27 of the Food Safety Act 1990;
- (f) a sampling officer within the meaning of Schedule 3 to the Medicines Act 1968;
- (g) a person employed or engaged in connection with a scheme for testing the quality or amount of the drugs, preparations and appliances supplied under the National Health Service Act 1977 or the National Health Service (Scotland) Act 1978 and the regulations made thereunder;
- (h) a person authorised by the Pharmaceutical Society of Great Britain for the purposes of section 108 or 109 of the Medicines Act 1968,
- (i) a supplementary prescriber acting under and in accordance with the terms of a clinical management plan,<sup>82</sup>

may, when acting in his capacity as such, supply or offer to supply any drug specified in Schedule 3 or 4 to any person who may lawfully have that drug in his possession.

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<sup>79</sup> Inserted by SI 2005/2864

<sup>80</sup> Inserted by SI 2003/2429

<sup>81</sup> Inserted by SI 2003/2429

<sup>82</sup> Inserted by 2005/271

## SI 2001/3998 (Amended)

(3) Notwithstanding the provisions of section 4(1)(b) of the Act –

- (a) a person who is authorised as a member of a group, under and in accordance with the terms of his group authority and in compliance with any conditions attached thereto;
- (b) the person in charge or acting person in charge of a hospital or ~~nursing~~ care home;<sup>83</sup>
- (c) in the case of such a drug supplied to her by a person responsible for the dispensing and supply of medicines at that hospital or ~~nursing~~ care home, ~~sister or acting sister~~ senior registered nurse or acting senior registered nurse for the time being in charge of a ward, theatre or other department in a hospital or ~~nursing~~ care home,<sup>84</sup>

may, when acting in his capacity as such, supply or offer to supply any drug specified in Schedule 3, or any drug specified in Schedule 4 which is contained in a medicinal product, to any person who may lawfully have that drug in his possession, except that nothing in this paragraph authorises –

- (i) the person in charge or acting person in charge of a hospital or ~~nursing~~ care home, having a pharmacist responsible for the dispensing and supply of medicines, to supply or offer to supply any drug;<sup>85</sup>
- (ii) ~~sister or acting sister~~ senior registered nurse or acting senior registered nurse for the time being in charge of a ward, theatre or other department to supply any drug otherwise than for administration to a patient in that ward, theatre or department in accordance with the directions of a doctor ~~or~~ dentist, supplementary prescriber acting under and in accordance with the terms of a clinical management plan or, subject to paragraph (3A), a nurse independent prescriber; or<sup>86</sup>
- (iii) an operating department practitioner to supply any drug otherwise than for administration to a patient in a ward, theatre or other department in accordance with the directions of a doctor, dentist, supplementary prescriber acting under and in accordance with the terms of a clinical management plan or, subject to paragraph (3A), a nurse independent prescriber.<sup>87</sup>

(d) in the case of such a drug supplied to him by a person responsible for the dispensing and supply of medicines at a hospital, an operating department practitioner practising in that hospital;<sup>88</sup>

(3A) The directions given by a nurse independent prescriber referred to in paragraph (3)(ii) and (iii) shall relate only to a controlled drug which she may prescribe under regulation 6B and a purpose for which it may be prescribed under that regulation.<sup>89</sup>

(4) Notwithstanding the provisions of section 4(1)(b) of the Act –

- (a) a person who is authorised by a written authority issued by the Secretary of State under and for the purposes of this sub-paragraph and for the time being in force may, at the premises specified in that authority and in compliance with any conditions so specified, supply or offer to supply any drug specified in Schedule 3 or 4 to any person who may lawfully have that drug in his possession;
- (b) a person who is authorised under paragraph (1)(c) may supply or offer to supply any drug which he may, by virtue of being so authorised, lawfully produce to any person who may lawfully have that drug in his possession.

(5) Notwithstanding the provisions of section 4(1)(b) of the Act –

- (a) the owner of a ship, or the master of a ship which does not carry a doctor among the seamen employed in it;
- (b) the installation manager of an offshore installation,

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<sup>83</sup> Amended by SI 2007/2154

<sup>84</sup> Amended by SI 2007/2154

<sup>85</sup> Amended by SI 2007/2154

<sup>86</sup> Amended by SI 2007/2154

<sup>87</sup> Inserted by SI 2007/2154

<sup>88</sup> Inserted by SI 2007/2154

<sup>89</sup> Inserted by SI 2007/2154

## SI 2001/3998 (Amended)

may supply or offer to supply any drug specified in Schedule 3, or any drug specified in Schedule 4 which is contained in a medicinal product –

- (i) for the purpose of compliance with any of the provisions specified in regulation 8(6), to any person on that ship or installation; or
  - (ii) to any person who may lawfully supply that drug to him.
- (6) Notwithstanding the provisions of section 4(1)(b) of the Act, a person in charge of a laboratory may, when acting in his capacity as such, supply or offer to supply any drug specified in Schedule 3 which is required for use as a buffering agent in chemical analysis to any person who may lawfully have that drug in his possession.
- ~~(7) Notwithstanding the provisions of section 4(1)(b) of the Act, an extended formulary nurse prescriber may, when acting in her capacity as such, supply or offer to supply diazepam, lorazepam and midazolam for use in palliative care to any person who may lawfully have any of these drugs in his possession.<sup>90</sup>~~
- (7) Notwithstanding the provisions of section 4(1)(b) of the Act, ~~an extended formulary nurse prescriber~~ a nurse independent prescriber<sup>91</sup> may, when acting in her capacity as such, supply or offer to supply—
- (a) diazepam, lorazepam and midazolam for use in palliative care or treatment of tonic-clonic seizures<sup>92</sup>;
  - (b) buprenorphine for transdermal use in palliative care; and
  - (c) chlordiazepoxide hydrochloride and diazepam for treatment of initial or acute withdrawal symptoms caused by the withdrawal of alcohol from persons habituated to it,
- to any person who may lawfully have any of these drugs in his possession.<sup>93</sup>
- (8) Notwithstanding the provisions of section 4(1)(b) of the Act, a registered nurse or a person specified in Schedule 8, when acting in their capacity as such, may supply or offer to supply, under and in accordance with the terms of a patient group direction, any drug specified in Schedule 4 **or Midazolam (with effect from 1 January 2008)**<sup>94</sup> to any person who may lawfully have that drug in his possession, except that this paragraph shall not have effect in the case of —
- (a) the supply or offer to supply of any of the anabolic steroid drugs specified in Part II of Schedule 4; and
  - (b) any drug or preparation which is designed for administration by injection and which is to be used for the purpose of treating a person who is addicted to a drug;
  - (c) for the purposes of paragraph (b) above, a person shall be regarded as being addicted to a drug if, and only if, he has as a result of repeated administration become so dependent upon the drug that he has an overpowering desire for the administration of it to be continued.<sup>95</sup>

### Possession of drugs in Schedules 2, 3 and 4

10. - (1) Notwithstanding the provisions of section 5(1) of the Act –

- (a) a person specified in one of sub-paragraphs (a) to ~~(j)~~ (k)<sup>96</sup> of regulation 8(2) may have in his possession any drug specified in Schedule 2;
- (b) a person specified in one of sub-paragraphs (a) to ~~(h)~~ (i)<sup>97</sup> of regulation 9(2) may have in his possession any drug specified in Schedule 3 or 4;

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<sup>90</sup> Inserted by SI 2003/2429, Deleted by SI 2005/2864

<sup>91</sup> Amended by SI 2006/986

<sup>92</sup> Amended by SI 2006/986

<sup>93</sup> Inserted by SI 2005/2864

<sup>94</sup> Amended by SI 2007/2154

<sup>95</sup> Inserted by SI 2003/2429

<sup>96</sup> Amended by SI 2005/271

<sup>97</sup> Amended by SI 2005/271

## SI 2001/3998 (Amended)

(c) a person specified in regulation 9(3)(b) to (d) ~~or (e)~~ or (6) may have in his possession any drug specified in Schedule 3,<sup>98</sup>

for the purpose of acting in his capacity as such a person, except that nothing in this paragraph authorises –

(i) a person specified in sub-paragraph (e) or (ea) of regulation 8(2);<sup>99</sup>

(ii) a person specified in sub-paragraph (c) or (d) of regulation 9(3);<sup>100</sup> or

(iii) a person specified in regulation 9(6),

to have in his possession any drug other than such a drug as is mentioned in the paragraph or sub-paragraph in question specifying him.

(d) a person specified in regulation 9(3)(b) to (d) ~~or (e)~~ may have in his possession any drug specified in Part I of Schedule 4 which is contained in a medicinal product;<sup>101</sup>

(e) a person specified in regulation 9(7) may have in her possession any drug specified in that regulation in accordance with the conditions specified in that regulation;<sup>102</sup>

(2) Notwithstanding the provisions of section 5(1) of the Act, a person may have in his possession any drug specified in Schedule 2, 3 or Part I of Schedule 4 for administration for medical, dental or veterinary purposes in accordance with the directions of a practitioner, a supplementary prescriber acting under and in accordance with the terms of a clinical management plan<sup>103</sup> or ~~an extended formulary nurse prescriber~~ a nurse independent prescriber<sup>104</sup>, except that this paragraph shall not have effect in the case of a person to whom the drug has been supplied by or on the prescription of a doctor, a supplementary prescriber<sup>105</sup> or ~~an extended formulary nurse prescriber~~ a nurse independent prescriber<sup>106</sup> if –

(a) that person was then being supplied with any controlled drug by or on the prescription of another doctor, another supplementary prescriber<sup>107</sup> or another ~~extended formulary nurse prescriber~~ nurse independent prescriber<sup>108</sup> and failed to disclose that fact to the first mentioned doctor, supplementary prescriber<sup>109</sup> or ~~extended formulary nurse prescriber~~ nurse independent prescriber<sup>110</sup> before the supply by him or on his prescription; or

(b) that or any other person on his behalf made a declaration or statement, which was false in any particular, for the purpose of obtaining the supply or prescription.<sup>111</sup>

(3) Notwithstanding the provisions of section 5(1) of the Act, a person who is authorised as a member of a group may, under and in accordance with the terms of his group authority and in compliance with any conditions attached thereto, have any drug specified in Schedule 2, 3 or Part I of Schedule 4 in his possession.

(4) Notwithstanding the provisions of section 5(1) of the Act –

(a) a person who is authorised by a written authority issued by the Secretary of State under and for the purposes of this sub-paragraph and for the time being in force may, at the premises specified in that authority and in compliance with any conditions so specified, have in his possession any drug specified in Schedule 3 or 4;

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<sup>98</sup> Amended by SI 2007/2154

<sup>99</sup> Amended by SI 2007/2154

<sup>100</sup> Amended by SI 2007/2154

<sup>101</sup> Inserted by SI 2003/2429, Amended by SI 2007/2154

<sup>102</sup> Inserted by SI 2003/2429

<sup>103</sup> Inserted by SI 2005/271

<sup>104</sup> Amended by SI 2006/986

<sup>105</sup> Inserted by SI 2005/271

<sup>106</sup> Amended by SI 2006/986

<sup>107</sup> Inserted by SI 2005/271

<sup>108</sup> Amended by SI 2006/986

<sup>109</sup> Inserted by SI 2005/271

<sup>110</sup> Amended by SI 2006/986

<sup>111</sup> Inserted by SI 2003/2429

## SI 2001/3998 (Amended)

(b) a person who is authorised under regulation 9(1)(c) may have in his possession any drug which he may, by virtue of being so authorised, lawfully produce;

(c) a person who is authorised under regulation 9(4)(a) may have in his possession any drug which he may, by virtue of being so authorised, lawfully supply or offer to supply.

(5) Notwithstanding the provisions of section 5(1) of the Act –

(a) any person may have in his possession any drug specified in Schedule 2, 3 or Part I of Schedule 4 for the purpose of compliance with any of the provisions specified in regulation 8(6);

(b) the master of a foreign ship which is in a port in Great Britain may have in his possession any drug specified in Schedule 2, 3 or Part I of Schedule 4 so far as necessary for the equipment of the ship.

(6) The foregoing provisions of this regulation are without prejudice to the provisions of regulation 4(3)(a).

### Exemption for midwives

11. - (1) Notwithstanding the provisions of sections 4(1)(b) and 5(1) of the Act, a registered midwife who has, in accordance with the provisions of rules made under ~~section 14(1)(b) of the Act of 1997~~ article 42 of the Order<sup>112</sup>, notified to the local supervising authority her intention to practise may, subject to the provisions of this regulation –

(a) so far as necessary to her professional practice, have in her possession;

(b) so far as necessary as aforesaid, administer; and

(c) surrender to the appropriate medical officer such stocks in her possession as are no longer required by her of,

any controlled drug which she may, under and in accordance with the provisions of the Medicines Act 1968 and of any instrument which is in force thereunder, lawfully administer.

(2) Nothing in paragraph (1) authorises a midwife to have in her possession any drug which has been obtained otherwise than on a midwife's supply order signed by the appropriate medical officer.

(3) In this regulation –

~~"the Act of 1997" means the Nurses, Midwives and Health Visitors Act 1997[13];~~<sup>113</sup>

"appropriate medical officer" means –

(a) a doctor who is for the time being authorised in writing for the purposes of this regulation by the local supervising authority for the region or area in which the drug was, or is to be, obtained; or

(b) for the purposes of paragraph (2), a person appointed under and in accordance with ~~section 15 of the Act of 1997~~ article 43 of the Order<sup>114</sup> by that authority to exercise supervision over registered midwives within their area, who is for the time being authorised as aforesaid;

"local supervising authority" has the meaning it is given by ~~section 15(1) of the Act of 1997~~ schedule 4 of the Order<sup>115</sup>;

"midwife's supply order" means an order in writing specifying the name and occupation of the midwife obtaining the drug, the purpose for which it is required and the total quantity to be obtained.

"the Order" means the Nursing and Midwifery Order 2001.<sup>116</sup>

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<sup>112</sup> Amended by SI 2004/1771

<sup>113</sup> Deleted by SI 2004/1771

<sup>114</sup> Amended by SI 2004/1771

<sup>115</sup> Amended by SI 2004/1771

<sup>116</sup> Inserted by SI 2004/1771



## SI 2001/3998 (Amended)

### Cultivation under licence of cannabis plant

12. Where any person is authorised by a licence of the Secretary of State issued under this regulation and for the time being in force to cultivate plants of the genus Cannabis, it shall not by virtue of section 6 of the Act be unlawful for that person to cultivate any such plant in accordance with the terms of the licence and in compliance with any conditions attached to the licence.

### Approval of premises for cannabis smoking for research purposes

13. Section 8 of the Act (which makes it an offence for the occupier of premises to permit certain activities there) shall not have effect in relation to the smoking of cannabis or cannabis resin for the purposes of research on any premises for the time being approved for the purpose under this regulation by the Secretary of State.

### Documents to be obtained by supplier of controlled drugs

14. - (1) Where a person (hereafter in this paragraph referred to as "the supplier"), not being a practitioner, supplies a controlled drug otherwise than on a prescription, the supplier shall not deliver the drug to a person who –
- (a) purports to be sent by or on behalf of the person to whom it is supplied (hereafter in this paragraph referred to as "the recipient"); and
  - (b) is not authorised by any provision of these Regulations other than the provisions of regulation 6(6) and (7)(f) to have that drug in his possession, unless that person produces to the supplier a statement in writing signed by the recipient to the effect that he is empowered by the recipient to receive that drug on behalf of the recipient, and the supplier is reasonably satisfied that the document is a genuine document.
- (2) Where a person (hereafter in this paragraph referred to as "the supplier")<sup>117</sup> supplies a controlled drug, otherwise than on a prescription or by way of administration, to any of the persons specified in paragraph (4), the supplier shall not deliver the drug –
- (a) until he has obtained a requisition in writing which –
    - (i) is signed by the person to whom the drug is supplied (hereafter in this paragraph referred to as "the recipient");
    - (ii) states the name, address and profession or occupation of the recipient;
    - (iii) specifies the purpose for which the drug supplied is required and the total quantity to be supplied; and
    - (iv) where appropriate, satisfies the requirements of paragraph (5);
  - (b) unless he is reasonably satisfied that the signature is that of the person purporting to have signed the requisition and that that person is engaged in the profession or occupation specified in the requisition, except that where the recipient is a practitioner and he represents that he urgently requires a controlled drug for the purpose of his profession, the supplier may, if he is reasonably satisfied that the recipient so requires the drug and is, by reason of some emergency, unable before delivery to furnish to the supplier a requisition in writing duly signed, deliver the drug to the recipient on an undertaking by the recipient to furnish such a requisition within the twenty-four hours next following.
- (3) A person who has given such an undertaking as aforesaid shall deliver to the person by whom the controlled drug was supplied a signed requisition in accordance with the undertaking.
- (4) The persons referred to in paragraph (2) are –
- (a) a practitioner;
  - (b) the person in charge or acting person in charge of a hospital or ~~nursing~~ care home;<sup>118</sup>
  - (c) a person who is in charge of a laboratory;

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<sup>117</sup> Amended by SI 2007/2154

<sup>118</sup> Amended by SI 2007/2154

## SI 2001/3998 (Amended)

- (d) the owner of a ship, or the master of a ship which does not carry a doctor among the seamen employed in it;
  - (e) the master of a foreign ship in a port in Great Britain;
  - (f) the installation manager of an offshore installation;
  - (g) a supplementary prescriber.<sup>119</sup>
- (5) A requisition furnished for the purposes of paragraph (2) shall –
- (a) where furnished by the person in charge or acting person in charge of a hospital or ~~nursing care home~~, be signed by a doctor or dentist employed or engaged in that hospital or ~~nursing care home~~;<sup>120</sup>
  - (b) where furnished by the master of a foreign ship, contain a statement, signed by the proper officer of the port health authority, or, in Scotland, the medical officer designated under section 14 of the National Health Service (Scotland) Act 1978 by the Health Board, within whose jurisdiction the ship is, that the quantity of the drug to be supplied is the quantity necessary for the equipment of the ship.
- (5A) **(with effect from 1 January 2008)** Subject to paragraph (5B), on receipt of a requisition (other than a veterinary requisition) mentioned in paragraph (2), the supplier shall—
- (a) mark on the requisition in ink or otherwise indelibly his name and address; and
  - (b) send the requisition to the relevant National Health Service agency in accordance with arrangements specified by that agency.<sup>121</sup>
- (5B) **(with effect from 1 January 2008)** Paragraph (5A) shall not apply where the supplier is—
- (a) a wholesale dealer; or
  - (b) a person responsible for the dispensing and supply of medicines at a hospital or care home.<sup>122</sup>
- (6) Where the person responsible for the dispensing and supply of medicines at any hospital or ~~nursing care home~~ supplies a controlled drug to the ~~sister or acting sister~~ senior registered nurse or acting senior registered nurse for the time being in charge of any ward, theatre or other department in that hospital or ~~nursing care home~~ (hereafter in this paragraph referred to as "the recipient") he shall<sup>123</sup> –
- (a) obtain a requisition in writing, signed by the recipient, which specifies the total quantity of the drug to be supplied; and
  - (b) mark the requisition in such manner as to show that it has been complied with, and any requisition obtained for the purposes of this paragraph shall be retained in the dispensary at which the drug was supplied and a copy of the requisition or a note of it shall be retained or kept by the recipient.
- (7) Nothing in this regulation shall have effect in relation to –
- (a) the drugs specified in Schedules 4 and 5 or poppy-straw;
  - (b) any drug specified in Schedule 3 contained in or comprising a preparation which –
    - (i) is required for use as a buffering agent in chemical analysis;
    - (ii) has present in it both a substance specified in paragraph 1 or 2 of that Schedule and a salt of that substance; and
    - (iii) is pre-mixed in a kit;
  - (c) any exempt product.

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<sup>119</sup> Inserted by SI 2005/271

<sup>120</sup> Amended by SI 2007/2154

<sup>121</sup> Inserted by SI 2007/2154

<sup>122</sup> Inserted by SI 2007/2154

<sup>123</sup> Amended by SI 2007/2154

## SI 2001/3998 (Amended)

- (8) **(with effect from 1 January 2008)** In this regulation, "veterinary requisition" means a requisition which states, in accordance with paragraph (2)(ii), that the recipient is a veterinary surgeon or veterinary practitioner.<sup>124</sup>

### Form of prescriptions

15. - (1) Subject to the provisions of this regulation, a person shall not issue a prescription containing a controlled drug other than a drug specified in Schedule 4 or 5 or temazepam unless the prescription complies with the following requirements, that is to say, it shall –
- ~~(a) be in ink or otherwise so as to be indelible and be signed by the person issuing it with his usual signature and dated by him;~~<sup>125</sup>
  - (a) be written so as to be indelible, be dated and be signed by the person issuing it with his usual signature;<sup>126</sup>
    - (aa) except in the case of a health prescription, be written on a prescription form provided by a Primary Care Trust or equivalent body for the purposes of private prescribing;<sup>127</sup>
    - (ab) except in the case of a health prescription or a veterinary prescription, specify the prescriber identification number of the person issuing it;<sup>128</sup>
  - ~~(b) insofar as it specifies the information required by sub paragraphs (c) and (f) below to be specified, be written by the person issuing it in his own handwriting;~~<sup>129</sup>
  - (c) except in the case of a health prescription, specify the prescriber identification number and the address of the person issuing it;<sup>130</sup>
  - (d) if issued by a dentist, have the words "for dental treatment only" written on it and, if issued by a veterinary surgeon or a veterinary practitioner, have a declaration written on it that the controlled drug is prescribed for an animal or herd under his care;
  - (e) specify the name and address of the person for whose treatment it is issued or, if it is issued by a veterinary surgeon or veterinary practitioner, of the person to whom the controlled drug prescribed is to be delivered;
  - (f) specify the dose to be taken and –
    - (i) in the case of a prescription containing a controlled drug which is a preparation, the form and, where appropriate, the strength of the preparation, and either the total quantity (in both words and figures) of the preparation or the number (in both words and figures) of dosage units, as appropriate, to be supplied;
    - (ii) in any other case, the total quantity (in both words and figures) of the controlled drug to be supplied;
  - (g) in the case of a prescription for a total quantity intended to be supplied by instalments, contain a direction specifying the amount of the instalments of the total amount which may be supplied and the intervals to be observed when supplying.
- (1A) A person shall not issue a prescription other than a health prescription or a veterinary prescription containing temazepam unless it is written on a prescription form provided by a Primary Care Trust or equivalent body for the purposes of private prescribing and it specifies the prescriber identification number and the address of the person issuing it.<sup>131</sup>
- (1B) Nothing in this regulation prevents the issue of a prescription, other than a health prescription, which is not written on a prescription form provided by a Primary Care Trust or equivalent body for the purposes of private prescribing, containing a controlled drug other than a drug specified in

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<sup>124</sup> Inserted by SI 2007/2154

<sup>125</sup> Deleted by SI 2005/2864

<sup>126</sup> Inserted by SI 2005/2864

<sup>127</sup> Inserted by SI 2006/1450

<sup>128</sup> Inserted by SI 2006/2178

<sup>129</sup> Deleted by SI 2005/2864

<sup>130</sup> Amended by SI 2006/1450, Amended by SI 2006/2178

<sup>131</sup> Inserted by SI 2006/1450, Amended by SI 2006/2178

## SI 2001/3998 (Amended)

Schedule 4 or 5, where the person issuing the prescription believes on reasonable grounds that the drug will be supplied by a pharmacist in a hospital.<sup>132</sup>

~~(2) Paragraph (1)(b) shall not have effect in relation to—~~

~~(a) a prescription issued by a person approved (whether personally or as a member of a class) for the purposes of this paragraph by the Secretary of State; or~~

~~(b) a prescription containing no controlled drug other than—~~

~~(i) phenobarbitone;~~

~~(ii) phenobarbitone sodium; or~~

~~(iii) a preparation containing a drug specified in paragraph (i) or (ii) above.<sup>133</sup>~~

(3) In the case of a prescription issued for the treatment of a patient in a hospital or nursing care home, it shall be a sufficient compliance with paragraph (1)(e) if the prescription is written on the patient's bed card or case sheet.<sup>134</sup>

### Provisions as to supply on prescription

16. - (1) ~~A~~ Subject to paragraph (5), a person shall not supply a controlled drug other than a drug specified in Schedule 4 or 5 on a prescription<sup>135</sup> —

(a) subject to paragraphs (1A) and (1C), unless the prescription complies with the provisions of regulation 15;<sup>136</sup>

(b) unless the address specified in the prescription as the address of the person issuing it is an address within the United Kingdom;

(c) unless he either is acquainted with the signature of the person by whom it purports to be issued and has no reason to suppose that it is not genuine, or has taken reasonably sufficient steps to satisfy himself that it is genuine;

(d) before the appropriate date ~~specified in the prescription;~~<sup>137</sup>

(e) subject to paragraph ~~(3)~~ (4), later than ~~thirteen weeks~~ twenty-eight days after the appropriate date ~~specified in the prescription.~~<sup>138</sup>

(1A) A pharmacist may supply a controlled drug other than a drug specified in Schedule 4 or 5 or temazepam if the prescription contains minor typographical errors or spelling mistakes or if it does not comply with the provisions of regulation 15 in the way specified in paragraph (1B), provided that—

(a) having exercised all due diligence, he is satisfied on reasonable grounds that the prescription is genuine;

(b) having exercised all due diligence, he is satisfied on reasonable grounds that he is supplying the drug in accordance with the intention of the person issuing the prescription;

(c) he amends the prescription in ink or otherwise indelibly to correct the minor typographical errors or spelling mistakes or so that the prescription complies with the requirements of regulation 15 as the case may be; and

(d) he marks the prescription so that the amendment he has made under sub-paragraph (c) is attributable to him.<sup>139</sup>

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<sup>132</sup> Inserted by SI 2006/1450

<sup>133</sup> Deleted by SI 2005/2864

<sup>134</sup> Amended by SI 2007/2154

<sup>135</sup> Inserted by SI 2006/1450

<sup>136</sup> Inserted by SI 2006/1450

<sup>137</sup> Inserted by SI 2006/1450,

<sup>138</sup> Amended by SI 2003/1653, Inserted by SI 2006/1450

<sup>139</sup> Inserted by SI 2006/1450

## SI 2001/3998 (Amended)

- (1B) The way specified in paragraph (1A) is that, in relation to regulation 15(1)(f), the total quantity of the preparation or of the controlled drug or the number of dosage units as the case may be is specified in either words or figures but not both.<sup>140</sup>
- (1C) A pharmacist may supply a controlled drug other than a drug specified in Schedule 4 or 5 on a prescription other than a health prescription in a hospital if it does not comply with regulation 15 in the ways specified in paragraph (1D).<sup>141</sup>
- (1D) The ways specified in paragraph (1C) are—
- (a) the prescription is not written on a prescription form provided by a Primary Care Trust or equivalent body for the purposes of private prescribing;
  - (b) the prescription does not specify the prescriber identification number of the person issuing it.<sup>142</sup>
- (2) Subject to paragraphs (3) and (4), a person supplying on prescription a controlled drug other than a drug specified in Schedule 4 or 5 shall, at the time of the supply, mark on the prescription the date on which the drug is supplied and, if it is a veterinary prescription ~~unless it is a health prescription~~, shall retain the prescription on the premises from which the drug was supplied.<sup>143</sup>
- (3) A person supplying temazepam on prescription in accordance with a prescription form of a kind specified in regulation 2A(1)(a)(i) of the National Health Service (Pharmaceutical Services) Regulations 1992 shall, at the time of the supply, enter on the form by electronic means the date on which the drug is supplied.
- (4) In the case of a prescription containing a controlled drug other than a drug specified in Schedule 4 or 5, which contains a direction that specified instalments of the total amount may be supplied at stated intervals, the person supplying the drug shall not do so otherwise than in accordance with that direction, and —
- (a) paragraph (1) shall have effect as if for the requirement contained in sub-paragraph (e) thereof there were substituted a requirement that the occasion on which the first instalment is supplied shall not be later than ~~thirteen weeks~~ twenty-eight days after the appropriate date ~~specified in the prescription~~;<sup>144</sup>
  - (b) paragraph (2) shall have effect as if for the words "at the time of the supply" there were substituted the words "on each occasion on which an instalment is supplied".
- (5) A person shall not supply a controlled drug specified in Schedule 4 on a prescription later than twenty-eight days after the appropriate date.<sup>145</sup>
- (6) A person who is asked to supply on prescription a controlled drug specified in Schedule 2 must first ascertain whether the person collecting the drug is the patient, the patient's representative or a healthcare professional acting in his professional capacity on behalf of the patient; and—
- (a) where that person is the patient or the patient's representative, he may—
    - (i) request evidence of that person's identity; and
    - (ii) refuse to supply the drug if he is not satisfied as to the identity of that person;
  - (b) where that person is a healthcare professional acting in his professional capacity on behalf of the patient, he—
    - (i) must obtain that person's name and address;
    - (ii) must, unless he is acquainted with that person, request evidence of that person's identity; but
    - (iii) may supply the drug even if he is not satisfied as to the identity of that person.

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<sup>140</sup> Inserted by SI 2006/1450

<sup>141</sup> Inserted by SI 2006/1450

<sup>142</sup> Inserted by SI 2006/1450

<sup>143</sup> Amended by SI 2006/2178

<sup>144</sup> Inserted by SI 2006/1450

<sup>145</sup> Inserted by SI 2006/1450

## SI 2001/3998 (Amended)

(7) In this regulation—

“appropriate date” means the later of the date on which it was signed by the person issuing it or the date indicated by him as being the date before which it shall not be supplied;

“healthcare professional” has the same meaning as in the National Health Service Act 1977;

“patient” means the person named in the prescription as the person to whom the drug is to be supplied;

“patient’s representative” means a person sent by or on behalf of the patient (other than a healthcare representative acting in his professional capacity).<sup>146</sup>

### Exemption for certain prescriptions

17. Nothing in regulations 15 and 16 shall have effect in relation to a prescription issued for the purposes of a scheme for testing the quality or amount of the drugs, preparations and appliances supplied under the National Health Service Act 1977 or the National Health Service (Scotland) Act 1978 and the regulations made thereunder or to any prescriptions issued for the purposes of the Medicines Act 1968 to a sampling officer within the meaning of that Act.

### Marking of bottles and other containers

18. - (1) Subject to paragraph (2), no person shall supply a controlled drug otherwise than in a bottle, package or other container which is plainly marked –

(a) in the case of a controlled drug other than a preparation, with the amount of the drug contained therein;

(b) in the case of a controlled drug which is a preparation –

(i) made up into tablets, capsules or other dosage units, with the amount of each component (being a controlled drug) of the preparation in each dosage unit and the number of dosage units in the bottle, package or other container;

(ii) not made up as aforesaid, with the total amount of the preparation in the bottle, package or other container and the percentage of each of its components which is a controlled drug.

(2) Nothing in this regulation shall have effect in relation to –

(a) the drugs specified in Schedules 4 and 5 or poppy-straw;

(b) any drug specified in Schedule 3 contained in or comprising a preparation which –

(i) is required for use as a buffering agent in chemical analysis;

(ii) has present in it both a substance specified in paragraph 1 or 2 of that Schedule and a salt of that substance; and

(iii) is premixed in a kit;

(c) any exempt product;

(d) the supply of a controlled drug by or on the prescription of a practitioner or supplementary prescriber<sup>147</sup>;

(e) the supply of a controlled drug for administration in a clinical trial or a medicinal test on animals.

(3) ~~In this regulation, the expressions “clinical trial” and “medicinal test on animals” have the same meanings as in the Medicines Act 1968.~~ In this regulation—

“clinical trial” has the same meaning as in the Medicines for Human Use (Clinical Trials) Regulations 2003;

“medicinal test on animals” has the same meaning as in the Medicines Act 1968.<sup>148</sup>

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<sup>146</sup> Inserted by SI 2006/1450

<sup>147</sup> Inserted by SI 2005/271

<sup>148</sup> Amended by SI 2004/1031

## SI 2001/3998 (Amended)

### Record-keeping requirements in respect of drugs in Schedules 1 and 2

19. - (1) Subject to paragraph (3) and regulation 21, every person authorised by or under regulation 5 or 8 to supply any drug specified in Schedule 1 or 2 shall comply with the following requirements, that is to say –

(a) he shall, in accordance with the provisions of this regulation and of regulation 20, keep a register and shall enter therein in chronological sequence ~~in the form specified in Part I or Part II of Schedule 6, as the case may require~~ subject to paragraph (f), using the headings specified in subparagraphs (d) and (e), **(with effect from 1 February 2008)**<sup>149</sup>, particulars of every quantity of a drug specified in Schedule 1 or 2 obtained by him and of every quantity of such a drug supplied (whether by way of administration or otherwise) by him whether to persons within or outside Great Britain;

(b) he shall use a separate register or separate part of the register for entries made in respect of each class of drugs, and each of the drugs specified in paragraphs 1 and 3 of Schedule 1 and paragraphs 1, 3 and 6 of Schedule 2 together with its salts and any preparation or other product containing it or any of its salts shall be treated as a separate class, so however that any stereoisomeric form of a drug or its salts shall be classed with that drug.

(c) **(with effect from 1 January 2007 2008**<sup>150</sup>) in the case of drugs specified in Schedule 2, where the drug was supplied on prescription, he shall in addition enter into the register in the form specified in Part II of Schedule 6, whether the person who collected the drug was the patient, the patient's representative or a healthcare professional acting on behalf of the patient and —

(i) if the person who collected the drug was a healthcare professional acting on behalf of the patient, that person's name and address; or

(iii) if the person who collected the drug was the patient or the patient's representative, whether evidence of identity was requested of that person;

and whether evidence of identity was provided by the person collecting the drug.<sup>151</sup>

(d) **(with effect from 1 February 2008)**The headings in respect of entries made for drugs obtained are—

(i) Date supply received;

(ii) Name and address from whom received;

(iii) Quantity received.<sup>152</sup>

(e) **(with effect from 1 February 2008)**The headings in respect of entries made for drugs supplied are—

(i) Date supplied;

(ii) Name/Address of person or firm supplied;

(iii) Details of authority to possess – prescriber or licence holder's details;

(iv) Quantity supplied;

(v) Person collecting Schedule 2 controlled drug (patient/ patient's rep / healthcare professional) and if healthcare professional, name and address;

(vi) Was proof of identity requested of patient/ patient's rep (Yes/No);

(vii) Was proof of identity of person collecting provided (Yes/No).<sup>153</sup>

(f) **(with effect from 1 February 2008)**The headings at subparagraph (e)(v) to (vii) apply only in respect of drugs specified in Schedule 2.<sup>154</sup>

<sup>149</sup> Amended by SI 2007/2154

<sup>150</sup> Amended by SI 2006/2178

<sup>151</sup> Inserted by SI 2006/1450

<sup>152</sup> Inserted by SI 2007/2154

<sup>153</sup> Inserted by SI 2007/2154

## SI 2001/3998 (Amended)

- (2) ~~Nothing in paragraph (1) shall be taken as preventing the use of a separate section within a register or separate part of a register in respect of different drugs or strengths of drugs comprised within the class of drugs to which that register or separate part relates. (deleted with effect from 1 February 2008)~~<sup>155</sup>
- (2) Entries made in respect of drugs obtained and drugs supplied may be made on the same page or on separate pages in the register. **(with effect from 1 February 2008)**<sup>156</sup>
- (2A) Subject to regulation 20(e), nothing in paragraphs (1) ~~and (2)~~ **(amended with effect from 1 February 2008)** shall prevent the use of a register to record additional information to that required or allowed under those provisions.<sup>157</sup>
- (3) The foregoing provisions of this regulation shall not have effect in relation to –
- (a) in the case of a drug supplied to him for the purpose of destruction in pursuance of regulation 6(2) or (3), a practitioner or pharmacist;
  - (b) a person licensed under regulation 5 to supply any drug, where the licence so directs; or
  - (c) the ~~sister or acting sister~~ senior registered nurse or acting senior registered nurse for the time being in charge of a ward, theatre or other department in a hospital or ~~nursing~~ care home.<sup>158</sup>

### Requirements as to registers

20. Any person required to keep a register under regulation 19 shall comply with the following requirements, that is to say –
- (a) in the separate register or separate part of the register used for each class of drug, a separate page shall be used in respect of each strength and form of that drug and the head of each such page shall specify the class of the drug, its strength and form ~~the class of drugs to which the entries on any page of any such register relate shall be specified at the head of that page~~ **(amended with effect from 1 February 2008);**<sup>159</sup>
  - (b) every entry required to be made under regulation 19 in such a register shall be made on the day on which the drug is obtained or, as the case may be, on which the transaction in respect of the supply of the drug by the person required to make the entry takes place or, if that is not reasonably practicable, on the day next following that day;
  - (c) no cancellation, obliteration or alteration of any such entry shall be made, and a correction of such an entry shall be made only by way of marginal note or footnote which shall specify the date on which the correction is made;
  - ~~(d) every such entry and every correction of such an entry shall be made in ink or otherwise so as to be indelible;~~<sup>160</sup>
  - (d) every such entry and every correction of such an entry shall be made in ink or otherwise so as to be indelible or shall be in a computerised form in which every such entry is attributable and capable of being audited and which is in accordance with best practice guidance endorsed by the Secretary of State under section 2 of the National Health Service Act 1977;<sup>161</sup>
  - (e) such a register shall not be used for any purpose other than ~~the purposes of~~ purposes related to these Regulations;<sup>162</sup>
  - (f) a separate register shall be kept in respect of each premises at which the person required to keep the register carries on his business or occupation, but subject to that not more than one register shall be kept at one time in respect of each class of drugs in respect of which he is required to keep a separate register, so, however, that a separate register may, with the

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<sup>154</sup> Inserted by SI 2007/2154

<sup>155</sup> Deleted by SI 2007/2154

<sup>156</sup> Inserted by SI 2007/2154

<sup>157</sup> Inserted by SI 2006/1450, Amended by SI 2007/2154

<sup>158</sup> Amended by SI 2007/2154

<sup>159</sup> Amended by SI 2007/2154

<sup>160</sup> Deleted by SI 2005/2864

<sup>161</sup> Inserted by SI 2005/2864

<sup>162</sup> Amended by SI 2006/1450



## SI 2001/3998 (Amended)

approval of the Secretary of State, be kept in respect of each department of the business carried on by him;

- (g) every such register in which entries are currently being made shall be kept at the premises to which it relates and, where the register is in computerised form, be accessible from those premises.<sup>163</sup>

### Record-keeping requirements in respect of drugs in Schedule 2 in particular cases

21. - (1) Where a drug specified in Schedule 2 is supplied in accordance with regulation 8(5)(a)(i) to any person on a ship, an entry in the official log book required to be kept under the Merchant Shipping Act 1995 or, in the case of a ship which is not required to carry such an official logbook, a report signed by the master of the ship, shall, notwithstanding anything in these Regulations, be a sufficient record of the supply if the entry or report specifies the drug supplied and, in the case of a report, it is delivered as soon as may be to a superintendent at a Marine Office established and maintained under the Merchant Shipping Act 1995.
- (2) Where a drug specified in Schedule 2 is supplied in accordance with regulation 8(5)(b)(i) to a person on an offshore installation, an entry in the installation logbook required to be maintained under the Offshore Installations (Logbooks and Registration of Death) Regulations 1972[14] which specifies the drug supplied shall, notwithstanding anything in these Regulations, be a sufficient record of the supply.
- (3) A midwife authorised by regulation 11(1) to have any drug specified in Schedule 2 in her possession shall –
- (a) on each occasion on which she obtains a supply of such a drug, enter in a book kept by her and used solely for the purposes of this paragraph the date, the name and address of the person from whom the drug was obtained, the amount obtained and the form in which it was obtained; and
- (b) on administering such a drug to a patient, enter in the said book as soon as practicable the name and address of the patient, the amount administered and the form in which it was administered.

### Record-keeping requirements in respect of drugs Schedules 3 and 4

22. - (1) Every person who is authorised under regulation 5 or 9(1)(c) to produce any drug specified in Schedule 3 or 4 shall make a record of each quantity of such a drug produced by him.
- (2) Every person who is authorised by or under any provision of the Act to import or export any drug specified in Schedule 3 shall make a record of each quantity of such a drug imported or exported by him.
- (3) Every person who is authorised under regulation 9(4) to supply any drug specified in Schedule 4 shall make a record of each quantity of such a drug imported or exported by him.
- (4) Paragraph (2) shall not have effect in relation to a person licensed under the Act to import or export any drug where the licence so directs.

### Preservation of registers, books and other documents

23. - (1) All registers and books kept in pursuance of regulation 19 or 21(3) shall be preserved for a period of two years from the date on which the last entry therein is made.
- (2) Every record made in pursuance of regulation 22 shall be preserved for a period of two years from the date on which the record was made.
- (3) Every ~~requisition, order and~~ **(Deleted with effect from 1/1/2008)**<sup>164</sup> veterinary prescription ~~or prescription (other than a health prescription)~~ on which a controlled drug is supplied in pursuance of these ~~regulations~~ Regulations<sup>165</sup> and every prescription (other than a health prescription) on which a controlled drug specified in Schedules 4 or 5 is so supplied, shall be preserved for a period of two years from the date on which the last delivery under it was made.<sup>166</sup>

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<sup>163</sup> Amended by SI 2005/2864

<sup>164</sup> Amended by SI 2007/2154

<sup>165</sup> Amended by SI 2007/2154

<sup>166</sup> Amended by SI 2006/2178

## SI 2001/3998 (Amended)

- (4) Every prescription (other than a health prescription or a veterinary prescription) on which a controlled drug other than a drug specified in Schedule 4 or 5 is supplied, ~~or a copy of such prescription, must~~ shall<sup>167</sup> be sent to the relevant National Health Service agency in accordance with arrangements specified by that agency.<sup>168</sup>

### Preservation of records relating to drugs in Schedules 3 and 5

24. - (1) A producer of any drug specified in Schedule 3 or 5 and a wholesale dealer in any such drug shall keep every invoice or other like record issued in respect of each quantity of such a drug obtained by him and in respect of each quantity of such a drug supplied by him.
- (2) A person who is authorised under regulation 9(4)(a) to supply any drug specified in Schedule 3 shall keep every invoice or other like record issued in respect of each quantity of such a drug obtained by him and in respect of each quantity of such a drug supplied by him.
- (3) A retail dealer in any drug specified in Schedule 3, a person in charge or acting person in charge of a hospital or ~~nursing~~ care home and a person in charge of a laboratory shall keep every invoice or other like record issued in respect of each quantity of such a drug obtained by him and in respect of each quantity of such a drug supplied by him.<sup>169</sup>
- (4) A retail dealer in any drug specified in Schedule 5 shall keep every invoice or other like record issued in respect of each quantity of such a drug obtained by him.
- (5) Every invoice or other record which is required by this regulation to be kept in respect of a drug specified in Schedule 3 shall contain information sufficient to identify the date of the transaction and the person by whom or to whom the drug was supplied.
- (6) Every document kept in pursuance of this regulation (other than a health prescription) shall be preserved for a period of two years from the date on which it is issued, except that the keeping of a copy of the document made at any time during the said period of two years shall be treated for the purposes of this paragraph as if it were the keeping of the original document.

### Preservation of records: supplementary

24A. For the purposes of regulations 23 and 24(6), “preserved” means kept in its original form, or copied and kept in a computerised form which is in accordance with best practice guidance endorsed by the Secretary of State under section 2 of the National Health Service Act 1977.<sup>170</sup>

### Exempt products

25. Nothing in regulations 19 to 24 shall have effect in relation to any exempt product.

### Furnishing of information with respect to controlled drugs

26. - (1) The persons specified in paragraph (2) shall on demand made by the Secretary of State or by any person authorised in writing by the Secretary of State in that behalf -
- (a) furnish such particulars as may be requested in respect of the producing, obtaining or supplying by him of any controlled drug or in respect of any stock of such drugs in his possession;
- (b) for the purpose of confirming any such particulars, produce any stock of such drugs in his possession;
- (c) produce any register, book or document required to be kept under these Regulations relating to any dealings in controlled drugs which is in his possession.
- (1A) For the purposes of paragraph (1)(c), the Secretary of State or any person authorised in writing by the Secretary of State in that behalf may request that a register which is kept in computerised form be produced by sending a copy of it, in computerised or other form, to the appropriate person.<sup>171</sup>
- (2) The persons referred to in paragraph (1) are -

<sup>167</sup> Amended by SI 2007/2154

<sup>168</sup> Inserted by SI 2006/1450, Amended by SI 2006/2178

<sup>169</sup> Amended by SI 2007/2154

<sup>170</sup> Inserted by SI 2005/2864

<sup>171</sup> Inserted by SI 2005/2864

## SI 2001/3998 (Amended)

- (a) any person authorised by or under these Regulations to produce any controlled drug;
  - (b) any person authorised by or under any provision of the Act to import or export any controlled drug;
  - (c) a wholesale dealer;
  - (d) a retail dealer;
  - (e) a practitioner;
  - (f) the person in charge or acting person in charge of a hospital or ~~nursing~~ care home;<sup>172</sup>
  - (g) a person who is in charge of a laboratory;
  - (h) a person who is authorised under regulation 9(4)(a) to supply any controlled drug;
  - (i) a supplementary prescriber.<sup>173</sup>
- (3) Nothing in this regulation shall require the furnishing of personal records which a person has acquired or created in the course of his profession or occupation and which he holds in confidence; and in this paragraph "personal records" means documentary and other records concerning an individual (whether living or dead) who can be identified from them and relating to his physical or mental health.

### Destruction of controlled drugs

27. - (1) No person who is required by any provision of, or by any term or condition of a licence having effect under, these Regulations to keep records with respect to a drug specified in Schedule 1, 2, 3 or 4 shall destroy such a drug or cause such a drug to be destroyed except in the presence of and in accordance with any directions given by a person authorised (whether personally or as a member of a class) for the purposes of this paragraph by the Secretary of State or, subject to paragraph (1A), an accountable officer<sup>174</sup> (hereafter in this regulation referred to as an "authorised person").
- (1A) An accountable officer shall not be an authorised person.<sup>175</sup>
- (2) An authorised person may, for the purposes of analysis, take a sample of a drug specified in Schedule 1, 2, 3 or 4 which is to be destroyed.
- (3) Where a drug specified in Schedule 1, 2, 3 or 4 is destroyed in pursuance of paragraph (1) by or at the instance of a person who is required by any provision of, or by any term or condition of a licence having effect under, these Regulations to keep a record in respect of the obtaining or supply of that drug, that record shall include particulars of the date of destruction and the quantity destroyed and shall be signed by the authorised person in whose presence the drug is destroyed.
- (4) Where the master or owner of a ship or installation manager of an offshore installation has in his possession a drug specified in Schedule 2 which he no longer requires, he shall not destroy the drug or cause it to be destroyed but shall dispose of it to a constable, or to a person who may lawfully supply that drug to him.
- (5) Nothing in paragraph (1) or (3) shall apply to any person who is required to keep records only by virtue of regulation 22(2) or (3) or 24(3).
- (6) Nothing in paragraph (1) or (3) shall apply to the destruction of a drug which has been supplied to a practitioner or pharmacist for that purpose in pursuance of regulation 6(2) or (3).

### Revocations

28. - (1) The regulations specified in Schedule 7 are hereby revoked.
- (2) Notwithstanding paragraph (1), any register, record, book, prescription or other document required to be preserved under regulation 23 or 24 of the Misuse of Drugs Regulations 1985[15] shall be preserved for the same period of time as if these Regulations had not been made.

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<sup>172</sup> Amended by SI 2007/2154

<sup>173</sup> Inserted by SI 2005/271

<sup>174</sup> Amended by SI 2007/2154

<sup>175</sup> Inserted by SI 2007/2154

## **SI 2001/3998 (Amended)**

- (3) In the case of a prescription issued before the coming into force of these Regulations, regulation 16(1) shall have effect as if -
- (a) in the case of a prescription containing a controlled drug other than a drug to which the provisions of regulation 15 of the Misuse of Drugs Regulations 1985 applied at the time the prescription was issued, sub-paragraphs (a) and (b) of that paragraph were omitted; and
  - (b) in any other case, for the said sub-paragraphs (a) and (b) there were substituted the words "unless the prescription complies with the provisions of the Misuse of Drugs Regulations 1985 relating to prescriptions".

Bob Ainsworth

Parliamentary Under-Secretary of State

Home Office

13th December 2001 (with subsequent amendments as noted)

## SI 2001/3998 (Amended)

### SCHEDULE 1 Regulation 3 CONTROLLED DRUGS SUBJECT TO THE REQUIREMENTS OF REGULATIONS 14, 15, 16, 18, 19, 20, 23, 26 AND 27

1. The following substances and products, namely -

(a) Bufotenine

Cannabinol

Cannabinol derivatives not being dronabinol or its stereoisomers

Cannabis and cannabis resin

Cathinone

Coca leaf

Concentrate of poppy-straw

<sup>176</sup>[2,3-Dihydro-5-methyl-3-(4-morpholinylmethyl)pyrrolo[1, 2, 3-*de*]-1,4-benzoxazin-6-yl]-1-naphthalenylmethanone

<sup>177</sup>3-Dimethylheptyl-11-hydroxyhexahydrocannabinol

Eticyclidine

Etryptamine

Fungus (of any kind) which contains psilocin or an ester of psilocin<sup>178</sup>

<sup>179</sup> [9-Hydroxy-6-methyl-3-[5-phenylpentan-2-yl] oxy-5, 6, 6a, 7, 8, 9, 10, 10a-octahydrophenanthridin-1-yl] acetate

<sup>180</sup>9-(Hydroxymethyl)-6, 6-dimethyl-3-(2-methyloctan-2-yl)-6a, 7, 10, 10a-tetrahydrobenzo[*c*]chromen-1-ol

Lysergamide

Lysergide and other N-alkyl derivatives of lysergamide

Mescaline

Methcathinone

<sup>181</sup>4-methylmethcathinone

Psilocin

Raw opium

Rolicyclidine

Tenocyclidine

4-Bromo-2,5-dimethoxy-*a*-methylphenethylamine

N,N-Diethyltryptamine

N,N-Dimethyltryptamine

2,5-Dimethoxy-,4-dimethylphenethylamine

N-Hydroxy-tenamphetamine

4-Methyl-aminorex

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<sup>176</sup> Inserted by SI 2009/3136

<sup>177</sup> Inserted by SI 2009/3136

<sup>178</sup> Inserted by SI 2005/1653

<sup>179</sup> Inserted by SI 2009/3136

<sup>180</sup> Inserted by SI 2009/3136

<sup>181</sup> Inserted by SI 2010/1144

## SI 2001/3998 (Amended)

- (b) any compound (not being a compound for the time being specified in sub-paragraph (a) above) structurally derived from tryptamine or from a ring-hydroxy tryptamine by substitution at the nitrogen atom of the sidechain with one or more alkyl substituents but no other substituent;
- (c) the following phenethylamine derivatives, namely -
- Allyl( $\alpha$ -methyl-3,4-methylenedioxyphenethyl)amine
  - 2-Amino-1-(2,5-dimethoxy-4-methylphenyl)ethanol
  - 2-Amino-1-(3,4-dimethoxyphenyl)ethanol
  - Benzyl(-methyl-3,4-methylenedioxyphenethyl)amine
  - 4-Bromo- $\beta$ ,2,5-trimethoxyphenethylamine
  - N-(4-sec-Butylthio-2,5-dimethoxyphenethyl)hydroxylamine
  - Cyclopropylmethyl( $\alpha$  -methyl-3,4-methylenedioxyphenethyl)amine
  - 2-(4,7-Dimethoxy-2,3-dihydro-1H-indan-5-yl)ethylamine
  - 2-(4,7-Dimethoxy-2,3-dihydro-1H-indan-5-yl)-1-methylethylamine
  - 2-(2,5-Dimethoxy-4-methylphenyl)cyclopropylamine
  - 2-(1,4-Dimethoxy-2-naphthyl)ethylamine
  - 2-(1,4-Dimethoxy-2-naphthyl)-1-methylethylamine
  - N-(2,5-Dimethoxy-4-propylthiophenethyl)hydroxylamine
  - 2-(1,4-Dimethoxy-5,6,7,8-tetrahydro-2-naphthyl)ethylamine
  - 2-(1,4-Dimethoxy-5,6,7,8-tetrahydro-2-naphthyl)-1-methylethylamine
  - $\alpha$ ,  $\alpha$  -Dimethyl-3,4-methylenedioxyphenethylamine
  - $\alpha$ ,  $\alpha$ -Dimethyl-3,4-methylenedioxyphenethyl(methyl)amine
  - Dimethyl( $\alpha$  -methyl-3,4-methylenedioxyphenethyl)amine
  - N-(4-Ethylthio-2,5-dimethoxyphenethyl)hydroxylamine
  - 4-Iodo-2,5-dimethoxy- $\alpha$ -methylphenethyl(dimethyl)amine
  - 2-(1,4-Methano-5,8-dimethoxy-1,2,3,4-tetrahydro-6-naphthyl)ethylamine
  - 2-(1,4-Methano-5,8-dimethoxy-1,2,3,4-tetrahydro-6-naphthyl)-1-methylethylamine
  - 2-(5-Methoxy-2,2-dimethyl-2,3-dihydrobenzo[b]furan-6-yl)-1-methylethylamine
  - 2-Methoxyethyl( $\alpha$  -methyl-3,4-methylenedioxyphenethyl)amine
  - 2-(5-Methoxy-2-methyl-2,3-dihydrobenzo[b]furan-6-yl)-1-methylethylamine
  - $\beta$ -Methoxy-3,4-methylenedioxyphenethylamine
  - 1-(3,4-Methylenedioxybenzyl)butyl(ethyl)amine
  - 1-(3,4-Methylenedioxybenzyl)butyl(methyl)amine
  - 2-( $\alpha$  -Methyl-3,4-methylenedioxyphenethylamino)ethanol
  - $\alpha$  -Methyl-3,4-methylenedioxyphenethyl(prop-2-ynyl)amine
  - N-Methyl-N-( $\alpha$  -methyl-3,4-methylenedioxyphenethyl)hydroxylamine
  - O-Methyl-N-( $\alpha$  -methyl-3,4-methylenedioxyphenethyl)hydroxylamine
  - $\alpha$  -Methyl-4-(methylthio)phenethylamine
  - $\beta$ ,3,4,5-Tetramethoxyphenethylamine
  - $\beta$ ,2,5-Trimethoxy-4-methylphenethylamine

## SI 2001/3998 (Amended)

- (d) any compound (not being methoxyphenamine or a compound for the time being specified in subparagraph (a) above) structurally derived from phenethylamine, an N-alkylphenethylamine,  $\alpha$ -methylphenethylamine, an N-alkyl- $\alpha$ -methylphenethylamine,  $\alpha$ -ethylphenethylamine, or an N-alkyl- $\alpha$ -ethylphenethylamine by substitution in the ring to any extent with alkyl, alkoxy, alkylendioxy or halide substituents, whether or not further substituted in the ring by one or more other univalent substituents;
- (e) any compound (not being a compound for the time being specified in Schedule 2) structurally derived from fentanyl by modification in any of the following ways, that is to say –
- (i) by replacement of the phenyl portion of the phenethyl group by any heteromonocycle whether or not further substituted in the heterocycle;
  - (ii) by substitution in the phenethyl group with alkyl, alkenyl, alkoxy, hydroxy, halogeno, haloalkyl, amino or nitro groups;
  - (iii) by substitution in the piperidine ring with alkyl or alkenyl groups;
  - (iv) by substitution in the aniline ring with alkyl, alkoxy, alkylendioxy, halogeno or haloalkyl groups;
  - (v) by substitution at the 4-position of the piperidine ring with any alkoxycarbonyl or alkoxyalkyl or acyloxy group;
  - (vi) by replacement of the N-propionyl group by another acyl group;
- (f) any compound (not being a compound for the time being specified in Schedule 2) structurally derived from pethidine by modification in any of the following ways, that is to say –
- (i) by replacement of the 1-methyl group by an acyl, alkyl whether or not unsaturated, benzyl or phenethyl group, whether or not further substituted;
  - (ii) by substitution in the piperidine ring with alkyl or alkenyl groups or with a propano bridge, whether or not further substituted;
  - (iii) by substitution in the 4-phenyl ring with alkyl, alkoxy, aryloxy, halogeno or haloalkyl groups;
  - (iv) by replacement of the 4-ethoxycarbonyl by any other alkoxycarbonyl or any alkoxyalkyl or acyloxy group;
  - (v) by formation of an N-oxide or of a quaternary base.
- <sup>182</sup>(g) 1-benzylpiperazine or any compound (not being a compound for the time being specified in Schedule 4) structurally derived from 1-benzylpiperazine or 1-phenylpiperazine by modification in any of the following ways—
- (i) by substitution at the second nitrogen atom of the piperazine ring with alkyl, benzyl, haloalkyl or phenyl groups;
  - (ii) by substitution in the aromatic ring to any extent with alkyl, alkoxy, alkylendioxy, halide or haloalkyl groups;
- (h) any compound structurally derived from 3-(1-naphthoyl)indole or 1*H*-indol-3-yl-(1-naphthyl)methane by substitution at the nitrogen atom of the indole ring by alkyl, alkenyl, cycloalkylmethyl, cycloalkylethyl or 2-(4-morpholinyl)ethyl, whether or not further substituted in the indole ring to any extent and whether or not substituted in the naphthyl ring to any extent;
- (i) any compound structurally derived from 3-(1-naphthoyl)pyrrole by substitution at the nitrogen atom of the pyrrole ring by alkyl, alkenyl, cycloalkylmethyl, cycloalkylethyl or 2-(4-morpholinyl)ethyl, whether or not further substituted in the pyrrole ring to any extent and whether or not substituted in the naphthyl ring to any extent;
- (j) any compound structurally derived from 1-(1-naphthylmethyl)indene by substitution at the 3-position of the indene ring by alkyl, alkenyl, cycloalkylmethyl, cycloalkylethyl or 2-(4-morpholinyl)ethyl, whether or not further substituted in the indene ring to any extent and whether or not substituted in the naphthyl ring to any extent;

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<sup>182</sup> Inserted by SI 2009/3136

## SI 2001/3998 (Amended)

(k) any compound structurally derived from 3-phenylacetylindole by substitution at the nitrogen atom of the indole ring with alkyl, alkenyl, cycloalkylmethyl, cycloalkylethyl or 2-(4-morpholinyl)ethyl, whether or not further substituted in the indole ring to any extent and whether or not substituted in the phenyl ring to any extent;

(l) any compound structurally derived from 2-(3-hydroxycyclohexyl)phenol by substitution at the 5-position of the phenolic ring by alkyl, alkenyl, cycloalkylmethyl, cycloalkylethyl or 2-(4-morpholinyl)ethyl, whether or not further substituted in the cyclohexyl ring to any extent.

(m)<sup>183</sup> Any compound (not being bupropion, diethylpropion, pyrovalerone or a compound for the time being specified in sub-paragraph (a) above) structurally derived from 2-amino-1-phenyl-1-propanone by modification in any of the following ways, that is to say –

(i) by substitution in the phenyl ring to any extent with alkyl, alkoxy, alkylendioxy, haloalkyl or halide substituents, whether or not further substituted in the phenyl ring by one or more other univalent substituents;

(ii) by substitution at the 3-position with an alkyl substituent;

(iii) by substitution at the nitrogen atom with alkyl or dialkyl groups, or by inclusion of the nitrogen atom in a cyclic structure.

(n)<sup>184</sup> Any compound structurally derived from 2-aminopropan-1-one by substitution at the -1 position with any monocyclic, or fused-polycyclic ring system (not being a phenyl ring or alkylendioxyphenyl ring system), whether or not the compound is further modified in any of the following ways, that is to say –

(i) by substitution in the ring system to any extent with alkyl, alkoxy, haloalkyl or halide substituents, whether or not further substituted in the ring system by one or more other univalent substituent;

(ii) by substitution at the 3-position with an alkyl substituent;

(iii) by substitution at the 2-amino nitrogen atom with alkyl or dialkyl groups, or by inclusion of the 2-amino nitrogen atom in a cyclic structure.

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

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

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.

### 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	Levophenacylmorphan
Alfentanil	Levorphanol
Allylprodine	Lofentanil
Alphacetylmethadol	Medicinal opium
Alphameprodine	Metazocine
Alphamethadol	Methadone
Alphaprodine	Methadyl acetate
Anileridine	Methyldesorphine
Benzethidine	Methyldihydromorphine (6-methyldihydromorphine)
Benzylmorphine (3-benzylmorphine)	Metopon
Betacetylmethadol	Morpheridine
Betameprodine	Morphine
Betamethadol	Morphine methobromide, morphine N-oxide and other pentavalent nitrogen morphine derivatives
Betaprodine	Myrophine

<sup>183</sup> Inserted by SI 2010/1144

<sup>184</sup> Inserted by SI 2010/1799



## SI 2001/3998 (Amended)

	<sup>185</sup> Nabilone
Bezitramide	Nicomorphine
Carfentanil	Noracymethadol
Clonitazene	Norlevorphanol
Cocaine	Normethadone
Desomorphine	Normorphine
Dextromoramide	Norpipanone
	<sup>186</sup> Oripavine
Diamorphine	Oxycodone
Diampromide	Oxymorphone
Diethylthiambutene	Pethidine
Difenoxin	Phenadoxone
Dihydrocodeinone O-carboxymethyloxime	Phenampramide
Dihydroetorphine <sup>187</sup>	Phenazocine
Dihydromorphine	Phencyclidine
Dimenoxadole	Phenomorphane
Dimepheptanol	Phenoperidine
Dimethylthiambutene	Piminodine
Dioxaphetyl butyrate	Piritramide
Diphenoxylate	Proheptazine
Dipipanone	Properidine
Dronabinol	Racemethorphan
Drotebanol	Racemoramide
Ecgonine, and any derivative of ecgonine which is convertible to ecgonine or to cocaine	Racemorphan
Ethylmethylthiambutene	Remifentanil <sup>188</sup>
Etonitazene	Sufentanil
Etorphine	Thebacon
Etoxadine	Thebaine
Fentanyl	Tilidate
Furethidine	Trimeperidine
Hydrocodone	Zipeprol
Hydromorhinol	4-Cyano-2-dimethylamino-4,4-diphenylbutane
Hydromorphone	Hydroxypethidine4-Cyano-1-methyl-4-piperidine
Isomethadonephenyl	2-Methyl-3-morpholino-1,1-diphenylpropane-carboxylic acid
Ketobemidone	<sup>α</sup> -Methylphenethylhydroxylamine
Levomethorphan	1-Methyl-4-phenylpiperidine-4-carboxylic acid
Levomoramide	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	Metahqualone
Amphetamine	Methylamphetamine
Codeine	Methylphenidate
Dextropropoxyphene	Nicocodine

<sup>185</sup> Inserted by SI 2009/3136

<sup>186</sup> Inserted by SI 2009/3136

<sup>187</sup> Inserted by SI 2003/1432

<sup>188</sup> Inserted by SI 2003/1432

## SI 2001/3998 (Amended)

Dihydrocodeine	Nicodicodine (6-nicotinoyldihydrocodeine)
Ethylmorphine (3-ethylmorphine)	Norcodeine
Fenethylamine	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	Midazolam <sup>189</sup>
Ethchlorvynol	Pentazocine
Ethinamate	Phendimetrazine
Flunitrazepam	Phentermine
Mazindol	Pipradrol
	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	4-Hydroxy-n-butyric acid <sup>190</sup>
Aminorex	Ketamine <sup>191</sup>
Bromazepam	Ketazolam
Brotizolam	Loprazolam
Camazepam	Lorazepam
Chlordiazepoxide	Lormetazepam
<sup>192</sup> 1-(3-chlorophenyl)piperazine	Medazepam
<sup>193</sup> 1-(3-chlorophenyl)-4-(3-chloropropyl)piperazine	Mefenorex

<sup>189</sup> Inserted by SI 2007/2154

<sup>190</sup> Inserted by SI 2003/1432

<sup>191</sup> Inserted by SI 2005/3372

<sup>192</sup> Inserted by SI 2009/3136

**SI 2001/3998 (Amended)**

Clobazam	Mesocarb
Clonazepam	<del>Midazolam</del> <sup>194</sup>
Lorazepam 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	Zolpidem <sup>195</sup>

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.

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<sup>193</sup> Inserted by SI 2009/3136

<sup>194</sup> Deleted by SI 2007/2154

<sup>195</sup> Inserted by SI 2003/1432

## SI 2001/3998 (Amended)

**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 -

<sup>196</sup> 5 $\alpha$ -Androstane-3,17-diol	Methandienone
<sup>197</sup> Androst-4-ene-3,17-diol	Methandriol
<sup>198</sup> 1-Androstenediol	Mesterolone
<sup>199</sup> 1-Androstenedione	Methenolone
4-Androstene-3, 17-dione <sup>200</sup>	Methyltestosterone
<sup>201</sup> 5-Androstenedione	Metribolone
5-Androstene-3, 17-diol <sup>202</sup>	Mibolerone
Atamestane	Nandrolone
Bolandiol	<sup>203</sup> 19-Norandrostenedione
Bolasterone	19-Nor-4-Androstene-3, 17-dione <sup>204</sup>
Bolazine	19-Nor-5-Androstene-3, 17-diol <sup>205</sup>
Boldenone	Norboletone
<sup>206</sup> Boldione	Norclostebol
Bolenol	Norethandrolone
Bolmantalate	<sup>207</sup> 19-Noretiocholanolone
Calusterone	Ovandroton
4-Chloromethandienone	Oxabolone
Clostebol	Oxandrolone
<sup>208</sup> Danazol	Oxymesterone
<sup>209</sup> Desoxymethyltestosterone	Oxymetholone
Drostanolone	Prasterone
Enestebol	Propetandrol
Epitiostanol	<sup>210</sup> Prostanozol
Ethyloestrenol	Quinbolone
Fluoxymesterone	Roxibolone

<sup>196</sup> Inserted by SI 2009/3136

<sup>197</sup> Inserted by SI 2009/3136

<sup>198</sup> Inserted by SI 2009/3136

<sup>199</sup> Inserted by SI 2009/3136

<sup>200</sup> Inserted by SI 2003/1432

<sup>201</sup> Inserted by SI 2009/3136

<sup>202</sup> Inserted by SI 2003/1432

<sup>203</sup> Inserted by SI 2009/3136

<sup>204</sup> Inserted by SI 2003/1432

<sup>205</sup> Inserted by SI 2003/1432

<sup>206</sup> Inserted by SI 2009/3136

<sup>207</sup> Inserted by SI 2009/3136

<sup>208</sup> Inserted by SI 2009/3136

<sup>209</sup> Inserted by SI 2009/3136

<sup>210</sup> Inserted by SI 2009/3136

## SI 2001/3998 (Amended)

Formebolone	Silandrone
Furazabol	Stanolone
<sup>211</sup> Gestrinone	Stanozolol
<sup>212</sup> 3-Hydroxy-5 $\alpha$ -androstan-17-one	Stenbolone
Mebolazine	Testosterone
Mepitiostane	<sup>213</sup> Tetrahydrogestrinone
Mesabolone	Thiomesterone
Mestanolone	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-hydroxyestrane-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
  - <sup>214</sup>Zeranol
  - <sup>215</sup>Zilpaterol
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.

### **SCHEDULE 5 Regulation 3 CONTROLLED DRUGS EXCEPTED FROM THE PROHIBITION ON IMPORTATION, EXPORTATION AND POSSESSION AND SUBJECT TO THE REQUIREMENTS OF REGULATIONS 24 AND 26**

1. - (1) Any preparation of one or more of the substances to which this paragraph applies, not being a preparation designed for administration by injection, when compounded with one or more other active or inert ingredients and containing a total of not more than 100 milligrams of the substance or substances (calculated as base) per dosage unit or with a total concentration of not more than 2.5% (calculated as base) in undivided preparations.
  - (2) The substances to which this paragraph applies are acetyldihydrocodeine, codeine, dihydrocodeine, ethylmorphine, nicocodine, nicodicodine (6-nicotinoyldihydrocodeine), norcodeine and pholcodine and their respective salts.

<sup>211</sup> Inserted by SI 2009/3136

<sup>212</sup> Inserted by SI 2009/3136

<sup>213</sup> Inserted by SI 2009/3136

<sup>214</sup> Inserted by SI 2009/3136

<sup>215</sup> Inserted by SI 2009/3136

## SI 2001/3998 (Amended)

- ~~2. Any preparation of cocaine containing not more than 0.1% of cocaine calculated as cocaine base, being a preparation compounded with one or more other active or inert ingredients in such a way that the cocaine cannot be recovered by readily applicable means or in a yield which would constitute a risk to health.~~<sup>216</sup>
3. Any preparation of medicinal opium or of morphine containing (in either case) not more than 0.2% of morphine calculated as anhydrous morphine base, being a preparation compounded with one or more other active or inert ingredients in such a way that the opium or, as the case may be, the morphine cannot be recovered by readily applicable means or in a yield which would constitute a risk to health.
4. Any preparation of dextropropoxyphene, being a preparation designed for oral administration, containing not more than 135 milligrams of dextropropoxyphene (calculated as base) per dosage unit or with a total concentration of not more than 2.5% (calculated as base) in undivided preparations.
5. Any preparation of difenoxin containing, per dosage unit, not more than 0.5 milligrams of difenoxin and a quantity of atropine sulphate equivalent to at least 5% of the dose of difenoxin.
6. Any preparation of diphenoxylate containing, per dosage unit, not more than 2.5 milligrams of diphenoxylate calculated as base, and a quantity of atropine sulphate equivalent to at least 1% of the dose of diphenoxylate.
7. Any preparation of propiram containing, per dosage unit, not more than 100 milligrams of propiram calculated as base and compounded with at least the same amount (by weight) of methylcellulose.
8. Any powder of ipecacuanha and opium comprising -
  - 10% opium, in powder,
  - 10% ipecacuanha root, in powder, well mixed with 80% of any other powdered ingredient containing no controlled drug.
9. Any mixture containing one or more of the preparations specified in paragraphs 1 to 8, being a mixture of which none of the other ingredients is a controlled drug.

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<sup>216</sup> Deleted by SI 2005/2864

**SCHEDULE 6 Regulation 19 FORM OF REGISTER**

(Schedule 6 deleted with effect from 1/2/2008) <sup>217</sup>

**PART I – Entries to be made in case of obtaining**

Date on which supply received	Name	Address	Amount obtained	Form in which obtained
	of person or firm from whom obtained			

**PART II – Entries to be made in case of supply**

Date on which transaction effected	Name	Address	Particulars as to licence or authority of person or firm supplied to be in possession	Amount supplied	Form in which supplied	Person collecting Schedule 2 controlled drug (patient / patient's rep / healthcare professional), and if healthcare professional, name and address	Was proof of identity requested of patient / patient's representative (Yes / No)	Was proof of identity of person collecting provided (Yes / No)
	of person or firm supplied					*	*	*

\* Columns effective from 1 January 2007 2008 <sup>218</sup>

<sup>217</sup> Whole Schedule deleted by SI 2007/2154 (with effect from 1/2/2008)

<sup>218</sup> Amended by SI 2006/2178

## SI 2001/3998 (Amended)

### SCHEDULE 7 Regulation 28 REGULATIONS REVOKED

Regulations revoked	References
The Misuse of Drugs Regulations 1985	S.I. 1985/2066
The Misuse of Drugs (Amendment) Regulations 1986	S.I. 1986/2330
The Misuse of Drugs (Amendment) Regulations 1988	S.I. 1988/916
The Misuse of Drugs (Amendment) Regulations 1989	S.I. 1989/1460
The Misuse of Drugs (Amendment) Regulations 1990	S.I. 1990/2630
The Misuse of Drugs (Amendment) Regulations 1995	S.I. 1995/2048
The Misuse of Drugs (Amendment No. 2) Regulations 1995	S.I. 1995/3244
The Misuse of Drugs (Amendment) Regulations 1996	S.I. 1996/1597
The Misuse of Drugs (Amendment) Regulations 1998	S.I. 1998/882
The Misuse of Drugs (Amendment) Regulations 1999	S.I. 1999/1404

### SCHEDULE 8 Regulations 8(8) and 9(8)

1. Any of the following persons may supply or administer a specified controlled drug under a patient group direction, namely—

- (a) a person who holds a certificate of proficiency in ambulance paramedic skills issued by, or with the approval of, the Secretary of State, or a person who is a ~~state~~ registered paramedic;<sup>219</sup>
- (b) ~~a registered health visitor;~~<sup>220</sup>
- (c) a registered midwife;
- (d) ~~a registered ophthalmic optician;~~ a registered optometrist;<sup>221</sup>
- (e) ~~a state registered chiropodist;~~ a registered chiropodist;<sup>222</sup>
- (f) ~~a person who is registered in the register of orthoptists maintained by the Health Professions Council pursuant to paragraph 11 of Schedule 2 to the Health Professions Order (a state registered orthoptist);~~ a registered orthoptist;<sup>223</sup>
- (g) ~~a person who is registered in the register of physiotherapists maintained by the Health Professions Council pursuant to paragraph 11 of Schedule 2 to the Health Professions Order (a state registered physiotherapist);~~ a registered physiotherapist;<sup>224</sup>
- (h) ~~a person who is registered in the register of radiographers maintained by the Health Professions Council pursuant to paragraph 11 of Schedule 2 to the Health Professions Order (a state registered radiographer);~~ a registered radiographer;<sup>225</sup>
- (i) a registered occupational therapist;<sup>226</sup>
- (j) a registered orthotist and prosthetist.<sup>227</sup>

Notes:

[1] 1971 c. 38.

[2] 1968 c. 64.

<sup>219</sup> Amended by SI 2007/2154

<sup>220</sup> Deleted by SI 2004/1771

<sup>221</sup> Amended by SI 2007/2154

<sup>222</sup> Amended by SI 2007/2154

<sup>223</sup> Amended by SI 2007/2154

<sup>224</sup> Amended by SI 2007/2154

<sup>225</sup> Inserted by SI 2003/2429, Amended by SI 2007/2154

<sup>226</sup> Inserted by SI 2006/1450

<sup>227</sup> Inserted by SI 2006/1450



## **SI 2001/3998 (Amended)**

- [3] 1977 c. 49.
- [4] 1978 c. 29.
- [5] S.I. 1972/1265 (N.I. 14).
- [6] 1971 c. 61.
- [7] 1995 c. 21.
- [8] 1968 c. 67.
- [9] 1979 c. 2.
- [10] 1981 c. 69.
- [11] 1990 c. 16.
- [12] 1974 c. 37.
- [13] 1997 c. 24.
- [14] S.I. 1972/1542.
- [15] S.I. 1985/2066.

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