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STATUTORY INSTRUMENTS

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**1997 No. 1830**

**MEDICINES**

**The Prescription Only Medicines (Human Use) Order 1997**

|                               |         |                         |
|-------------------------------|---------|-------------------------|
| <i>Made</i>                   | - - - - | <i>25th July 1997</i>   |
| <i>Laid before Parliament</i> |         | <i>28th July 1997</i>   |
| <i>Coming into force</i>      | - -     | <i>18th August 1997</i> |

The Secretary of State concerned with health in England, the Secretaries of State concerned with health and with agriculture in Wales and in Scotland respectively, the Minister of Agriculture, Fisheries and Food, the Department of Health and Social Services for Northern Ireland and the Department of Agriculture for Northern Ireland, acting jointly, in exercise of powers conferred on them by sections 58(1), (4) and (5), 59(1) and 129(4) of the Medicines Act 1968<sup>(1)</sup> or, as the case may be, those conferred by the said provisions and now vested in them<sup>(2)</sup>, and of all other powers enabling them in that behalf, after consulting such organisations as appear to them to be representative of interests likely to be substantially affected by this Order, pursuant to section 129(6) of that Act, and after consulting and taking into account the advice of the Medicines Commission pursuant to sections 58(6) and 129(7) of that Act, hereby make the following Order:

**Citation, commencement and interpretation**

1.—(1) This Order may be cited as the Prescription Only Medicines (Human Use) Order 1997 and shall come into force on 18th August 1997.

(2) In this Order, unless the context otherwise requires—

“the Act” means the Medicines Act 1968;

[<sup>F1</sup>“additional supply optometrist” means a person who is registered as an optometrist, and against whose name particulars of the additional supply speciality have been entered in the relevant register;]

“aerosol” means a product which is dispersed from its container by a propellant gas or liquid;

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(1) 1968 c. 67. Section 58 has been amended by the Prescription by Nurses Etc. Act 1992 (c. 28), section 1. The expression “the appropriate Ministers” is defined in section 1(2) of the Medicines Act 1968.

(2) In the case of the Secretaries of State concerned with health in England and in Wales by virtue of article 2(2) of, and Schedule 1 to, the Transfer of Functions (Wales) Order 1969 (S.I. 1969/388); in the case of the Secretary of State concerned with Agriculture in Wales by virtue of article 2(3) of, and Schedule 1 to, the Transfer of Functions (Wales) (No. 1) Order 1978 (S.I. 1978/272) and in the case of the Northern Ireland Departments by virtue of section 40 of, and Schedule 5 to, the Northern Ireland Constitution Act 1973 (c. 36) and section 1(3) of, and paragraph 2(1)(b) of Schedule 1 to, the Northern Ireland Act 1974 (c. 28).

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*Status: Point in time view as at 17/01/2011.*

*Changes to legislation: There are currently no known outstanding effects for the The Prescription Only Medicines (Human Use) Order 1997. (See end of Document for details)*

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[<sup>F2</sup>“clinical management plan” means a written plan (which may be amended from time to time) relating to the treatment of an individual patient agreed by—

- (a) the patient to whom the plan relates,
- (b) the doctor or dentist who is a party to the plan, and
- (c) any supplementary prescriber who is to prescribe, give directions for administration or administer under the plan;]

[<sup>F3</sup>“clinical trial” has the meaning given by regulation 2(1) of the Medicines for Human Use (Clinical Trials) Regulations 2003;]

<sup>F4</sup> ...

[<sup>F5</sup>“Common Services Agency” means the Common Services Agency for the Scottish Health Service established under section 10 of the National Health Service (Scotland) Act 1978;]

[<sup>F5</sup>“Community marketing authorization” means a marketing authorization granted by the European Community under Council Regulation (EEC) No. 2309/93<sup>F6</sup> or Regulation (EC) No. 726/2004 of the European Parliament and of the Council laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency;]

[<sup>F7</sup>“community practitioner nurse prescriber” means a person—

- (a) who is a registered nurse or a registered midwife, and
- (b) against whose name is recorded in the professional register an annotation signifying that he is qualified to order drugs, medicines and appliances from the Nurse Prescribers' Formulary for Community Practitioners in the current edition of the British National Formulary;]

“controlled drug” has the meaning assigned to it by section 2 of the Misuse of Drugs Act 1971(3);

“cyanogenetic substances” means preparations which—

- (a) are presented for sale or supply under the name of, or as containing, amygdalin, laetrile or vitamin B17, or
- (b) contain more than 0.1 per cent by weight of any substance having the formula either  $\alpha$ -Cyanobenzyl-6-O- $\beta$ -d-glucopyranosyl- $\beta$ -d-glucopyranoside or  $\alpha$ -Cyanobenzyl- $\beta$ -d-glucopyranosiduronic acid;

[<sup>F8</sup>“dental hygienist” means a person whose name is registered under the title of dental hygienist in the dental care professionals register;

“dental therapist” means a person whose name is registered under the title of dental therapist in the dental care professionals register;

“dental care professionals register” means the dental care professionals register established under section 36B of the Dentists Act 1984;]

<sup>F9</sup> ...

“dosage unit” means—

- (a) where a medicinal product is in the form of a tablet or capsule or is an article in some other similar pharmaceutical form, that tablet, capsule or other article, or
- (b) where a medicinal product is not in any such form, the unit of measurement which is used as the unit by reference to which the dose of the medicinal product is measured;

F10  
...

F11  
...

“external use” means application to the skin, hair, teeth, mucosa of the mouth, throat, nose, ear, eye, vagina or anal canal when a local action only is intended and extensive systemic absorption is unlikely to occur; and references to medicinal products for external use shall be read accordingly except that such references shall not include throat sprays, throat pastilles, throat lozenges, throat tablets, nasal drops, nasal sprays, nasal inhalations or teething preparations;

F12  
...

[F5“Health Authority”—

(a) F13  
...

(b) in relation to Scotland, means a Health Board constituted under section 2 of the National Health Service (Scotland) Act 1978; and

(c) in relation to Northern Ireland, means a Health and Social Services Board established under Article 16 of the Health and Personal Social Services (Northern Ireland) Order 1972;]

[F14“health care” means services for or in connection with the prevention, diagnosis or treatment of disease;]

“health prescription” means a prescription issued by a doctor, dentist [F15, supplementary prescriber] , [F16a community practitioner nurse prescriber, a nurse independent prescriber or a pharmacist independent prescriber] under or by virtue of—

(a) in England and Wales, the National Health Service Act 1977(4),

(b) in Scotland, the National Health Service (Scotland) Act 1978(5), and

(c) in Northern Ireland, the Health and Personal Social Services (Northern Ireland) Order 1972(6);

[F17“health record” has the meaning given by section 68(2) of the Data Protection Act 1998(6);]

[F5“homoeopathic certificate of registration” means a certificate of registration for the purposes of the Medicines (Homoeopathic Medicinal Products For Human Use) Regulations 1994;]

[F18“independent clinic”—

(a) [F19in relation to Wales], has the meaning given by section 2(4) of the Care Standards Act 2000(8), and

(b) in relation to Scotland, has the meaning given by section 77(1) of the Regulation of Care (Scotland) Act [F202001, and];]

(c) [F21in relation to Northern Ireland, has the meaning given by article 2(2) of the Health and Personal Social Services (Quality, Improvement and Regulation) (Northern Ireland) Order 2003;]

[F18“independent hospital”—

(za) [F22in relation to England, means a hospital as defined by section 275 of the National Health Service Act 2006 that is not a health service hospital as defined by that section,

(4) 1977 c. 49.

(5) 1978 c. 29.

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

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

(8) S.I. 1985/2066.

*Status: Point in time view as at 17/01/2011.*

*Changes to legislation: There are currently no known outstanding effects for the The Prescription Only Medicines (Human Use) Order 1997. (See end of Document for details)*

- (a) in relation to Wales, shall be construed in accordance with section 2(2), (3) and (6) of the Care Standards Act 2000,]
- (b) in relation to Scotland, means—
  - (i) an independent hospital, or
  - (ii) a private psychiatric hospital,
 as defined by section 77(1) of the Regulation of Care (Scotland) Act [<sup>F23</sup>2001, and]]
- (c) [<sup>F24</sup>in relation to Northern Ireland, has the meaning given by article 2(2) of the Health and Personal Social Services (Quality, Improvement and Regulation) (Northern Ireland) Order 2003;]

[<sup>F18</sup>“independent medical agency”—

- (a) [<sup>F25</sup>in relation to England and Wales, means an undertaking (not being an independent hospital, or in Wales an independent clinic) which consists of or includes the provision of services by medical practitioners and the term “undertaking” in this definition is to be interpreted in accordance with paragraph (2A),]
- (b) in relation to Scotland, has the meaning given by section 77(1) of the Regulation of Care (Scotland) Act [<sup>F26</sup>2001, and]]
- (c) [<sup>F27</sup>in relation to Northern Ireland, has the meaning given by article 2(2) of the Health and Personal Social Services (Quality, Improvement and Regulation) (Northern Ireland) Order 2003;]

“inhaler” does not include an aerosol;

[<sup>F28</sup>“IRME practitioner” means, in relation to a medical exposure, a practitioner for the purposes of the Ionising Radiation (Medical Exposure) Regulations 2000(4);]

[<sup>F29</sup>“Local Health Board” has the same meaning as in the National Health Service Act 1977;]

[<sup>F5</sup>“marketing authorization” includes a reference both to a United Kingdom marketing authorization and to a Community marketing authorization;]

“master” has the same meaning as in section 313(1) of the Merchant Shipping Act 1995(7);

“maximum daily dose” or “MDD” means the maximum quantity of a substance contained in the amount of a medicinal product which it is recommended should be taken or administered in a period of 24 hours;

“maximum dose” or “MD” means the maximum quantity of a substance contained in the amount of a medicinal product which it is recommended should be taken or administered at any one time;

“maximum strength” means—

- (a) the maximum quantity of a substance by weight or volume contained in a dosage unit of a medicinal product;
- (b) the maximum percentage of a substance contained in a medicinal product calculated in any of the following ways—
  - (i) weight in weight,
  - (ii) weight in volume,
  - (iii) volume in weight, or
  - (iv) volume in volume,

(4) 1977 c. 49.

(7) 1995 c. 21.

and if the maximum percentage calculated in those ways differs, the higher or highest such percentage;

[<sup>F30</sup>“medical exposure” has the same meaning as in the Ionising Radiation (Medical Exposure) Regulations 2000;]

“medicinal product” includes any article or substance in respect of which section 58 of the Act has effect by virtue of an order made under section 104 of the Act<sup>F31</sup>...

“the Misuse of Drugs Regulations” means, in relation to England, Wales and Scotland, the Misuse of Drugs Regulations 1985<sup>(8)</sup> and in relation to Northern Ireland, the Misuse of Drugs (Northern Ireland) Regulations 1986<sup>(9)</sup>;

[<sup>F5</sup>“NHS trust”—

- (a) in relation to England and Wales, has the same meaning as in the National Health Service and Community Care Act 1990;
- (b) in relation to Scotland, has the same meaning as in the National Health Service (Scotland) Act 1978; and
- (c) in relation to Northern Ireland, means a Health and Social Services trust established under article 10 of the Health and Social Services (Northern Ireland) Order 1991;]

[<sup>F32</sup>“nurse independent prescriber” means a person—

- (a) who is a registered nurse or a registered midwife, and
- (b) against whose name is recorded in the professional register an annotation signifying that he is qualified to order drugs, medicines and appliances as a nurse independent prescriber or a nurse independent/supplementary prescriber;]

[<sup>F33</sup>“NHS foundation trust” has the same meaning as in section 1(1) of the Health and Social Care (Community Health and Standards) Act 2003;]

[<sup>F34</sup>“nursing home” has the meaning given by article 16 [<sup>F35</sup>article 11 of the Health and Personal Social Services (Quality, Improvement and Regulation) (Northern Ireland) Order 2003];]

“occupational health scheme” means a scheme in which a person, in the course of a business carried on by him, provides facilities for his employees for the treatment or prevention of disease;

“offshore installation” means an offshore installation within the meaning of the Mineral Workings (Offshore Installations) Act 1971<sup>(10)</sup> which is within—

- (a) tidal waters and parts of the sea in or adjacent to the United Kingdom up to the seaward limits of territorial waters;
- (b) waters in any area designated under section 1(7) of the Continental Shelf Act 1964<sup>(11)</sup>;

[<sup>F36</sup>“operator”—

- (a) in relation to an aircraft, means the person for the time being having management of the aircraft, and
- (b) for the purposes of article 7B, has the same meaning as in the Ionising Radiation (Medical Exposure) Regulations 2000;]

[<sup>F37</sup>“optometrist independent prescriber” means a person—

- (a) who is a registered optometrist, and

(8) S.I. 1985/2066.

(9) SR 1986 No. 52.

(10) 1971 c. 61; section 1 was substituted by section 24 of the Oil and Gas (Enterprise) Act 1982 (c. 23).

(11) 1964 c. 29.

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*Changes to legislation: There are currently no known outstanding effects for the The Prescription Only Medicines (Human Use) Order 1997. (See end of Document for details)*

- (b) against whose name is recorded in the relevant register an annotation signifying that he is qualified to order drugs, medicines and appliances as an optometrist independent prescriber;]

“parenteral administration” means administration by breach of the skin or mucous membrane;

[<sup>F5</sup>“Patient Group Direction” means—

- (a) in connection with the [<sup>F38</sup>sale or] supply of a prescription only medicine as referred to in article 12A(2), [<sup>F39</sup>12B, 12C, 12D or 12E], a written direction relating to the [<sup>F40</sup>sale or supply, and administration,] of a description or class of prescription only medicine; or
- (b) in connection with the administration of a prescription only medicine as referred to in article 12A(2), 12B or 12C, a written direction relating to the administration of a description or class of prescription only medicine, and which, in the case of either (a) or (b)—
- (i) is signed by a doctor or dentist, and by a pharmacist; and
- (ii) relates to [<sup>F41</sup>sale or] supply and administration, or to administration, to persons generally (subject to any exclusions which may be set out in the Direction);]

[<sup>F42</sup>“pharmacist independent prescriber” means a person—

- (a) who is a pharmacist, and
- (b) against whose name is recorded in the relevant register an annotation signifying that he is qualified to order drugs, medicines and appliances as a pharmacist independent prescriber;]

“prescription only medicine” means a medicinal product of a description or falling within a class specified in article 3 of this Order;

[<sup>F5</sup>“Primary Care Trust” has the same meaning as in the National Health Service Act 1977;]

[<sup>F43</sup>“prison service” means—

- (a) in relation to England and Wales, a Minister of the Crown exercising functions in relation to prisons (within the meaning of the Prison Act 1952),
- (b) in relation to Scotland, the Scottish Ministers exercising functions in relation to prisons (within the meaning of the Prisons (Scotland) Act 1989), and
- (c) in relation to Northern Ireland, the Northern Ireland Department exercising functions in relation to prisons (within the meaning of the Prison Act (Northern Ireland) 1953);]

[<sup>F44</sup>“professional register” means the register maintained by the Nursing and Midwifery Council [<sup>F45</sup>under article 5 of] the Nursing and Midwifery Order 2001;]

“prolonged release” in relation to a medicinal product means a formulation of that product which—

- (a) is used to reduce the rate at which the active ingredient in that product is released after administration, and
- (b) is sold or supplied as a prolonged, controlled or sustained release medicinal product;

[<sup>F46</sup>“radioactive medicinal product” means a medicinal product which is, which contains or which generates a radioactive substance and which is, contains or generates that substance in order, when administered, to utilize the radiation emitted therefrom;]

[<sup>F47</sup>“registered chiropodist” means a person who is registered in Part 2 of the register maintained by the Health Professions Council under article 5 of the Health Professions Order 2001;]

[<sup>F48c</sup>“registered dietitian” means a person who is registered in Part 4 of the register maintained by the Health Professions Council under article 5 of the Health Professions Order 2001;]

[<sup>F49c</sup>“registered midwife” means a person registered in the Midwives' Part of the professional register;]

[<sup>F50c</sup>“registered nurse” means a person registered in the Nurses' Part [<sup>F51</sup>or Specialist Community Public Health Nurses' Part] of the professional register;]

[<sup>F48c</sup>“registered occupational therapist” means a person who is registered in Part 6 of the register maintained by the Health Professions Council under article 5 of the Health Professions Order 2001;]

[<sup>F52</sup> “registered optometrist” means a person whose name is registered in the register of optometrists maintained under section 7(a) of the Opticians Act 1989, or in the register of visiting optometrists from relevant European States maintained under section 8B(1)(a) of that Act;]

[<sup>F47c</sup>“registered orthoptist” means a person who is registered in Part 7 of the register maintained by the Health Professions Council under article 5 of the Health Professions Order 2001;];

[<sup>F48c</sup>“registered orthotist and prosthetist” means a person who is registered in Part 10 of the register maintained by the Health Professions Council under article 5 of the Health Professions Order 2001;]

[<sup>F47c</sup>“registered paramedic” means a person who is registered in Part 8 of the register maintained by the Health Professions Council under article 5 of the Health Professions Order 2001;]

[<sup>F47c</sup>“registered physiotherapist” means a person who is registered in Part 9 of the register maintained by the Health Professions Council under article 5 of the Health Professions Order 2001;]

[<sup>F53c</sup>“registered provider” means—

(a) in relation to an independent hospital, an independent clinic [<sup>F54</sup>in Wales, Scotland or Northern Ireland] or an independent medical agency—

(i) [<sup>F55</sup>in relation—

(aa) to England, the person who is registered under Chapter 2 of Part 1 of the Health and Social Care Act 2008 in respect of regulated activities (within the meaning of that Part) carried on in that hospital or agency, and

(bb) to Wales, the person who is registered under Part 2 of the Care Standards Act 2000 as the person carrying on the establishment or agency,]

(ii) in relation to Scotland, the person who is registered under Part 1 of the Regulation of Care (Scotland) Act 2001 as the person providing the establishment or agency, and

(iii) [<sup>F56</sup>in relation to Northern Ireland, the person registered under Part III of the Health and Personal Social Services (Quality, Improvement and Regulation) (Northern Ireland) Order 2003 as the person carrying on the establishment or agency, and]

(b) [<sup>F57</sup>in relation to a nursing home, the person registered under Part III of the Health and Personal Social Services (Quality, Improvement and Regulation) (Northern Ireland) Order 2003 as the person carrying on the establishment;]

[<sup>F47c</sup>“registered radiographer” means a person who is registered in Part 11 of the register maintained by the Health Professions Council under article 5 of the Health Professions Order 2001;]

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[<sup>F48c</sup>registered speech and language therapist” means a person who is registered in Part 12 of the register maintained by the Health Professions Council under article 5 of the Health Professions Order 2001;]

[<sup>F53c</sup>relevant manager” means—

- (a) in relation to an independent hospital, an independent clinic [<sup>F58</sup>in Wales, Scotland or Northern Ireland] or an independent medical agency—
  - (i) [<sup>F59</sup>in relation to England, a person who is registered under Chapter 2 of Part 1 of the Health and Social Care Act 2008 as a manager in respect of regulated activities (within the meaning of that Part) carried on in that hospital or agency, and
  - (ia) in relation to Wales—]
    - (aa) a person who is registered under Part II of the Care Standards Act 2000 as the manager of the establishment or agency, but who is not the registered provider for that establishment or agency, or
    - (bb) if there is no such person, but the registered provider has appointed a person to manage the establishment or agency, that appointed person,
  - (ii) in relation to Scotland, a person, other than the registered provider, who was identified as an individual who is to manage the establishment or agency on the application for registration of that establishment or agency under Part 1 of Regulation of Care (Scotland) Act 2001, and
  - (iii) [<sup>F60</sup>in relation to Northern Ireland—]
    - (aa) a person who is registered under Part III of the Health and Personal Social Services (Quality, Improvement and Regulation) (Northern Ireland) Order 2003 as the manager of the establishment or agency, but who is not the registered provider for that establishment or agency, or
    - (bb) if there is no such person, but the registered provider has appointed a person to manage the establishment or agency, that appointed person, and]
- (b) [<sup>F61</sup>in relation to a nursing home—]
  - (i) a person who is registered under Part III of the Health and Personal Social Services (Quality, Improvement and Regulation) (Northern Ireland) Order 2003 as the manager of the establishment or agency, but who is not the registered provider for that establishment or agency, or
  - (ii) if there is no such person, but the registered provider has appointed a person to manage the establishment or agency, that appointed person;]]

[<sup>F53c</sup>relevant register” means—

- (a) in relation to a [<sup>F62</sup>registered] nurse [<sup>F63</sup>or registered midwife], the professional register,  
<sup>F64</sup> ...
- (b) in relation to a pharmacist, [<sup>F65</sup>Part 1 of the register maintained under article 19 of the Pharmacy Order 2010] or the register maintained in pursuance of Articles 6 and 9 of the Pharmacy (Northern Ireland) Order 1976; <sup>F66</sup> ...
- (c) [<sup>F67</sup>in relation to a person whose name is registered in the part of the register maintained by the Health Professions Council in pursuance of article 5 of the Health Professions Order 2001 relating to—]
  - (i) chiropodists and podiatrists;
  - (ii) physiotherapists; or



(iii) radiographers diagnostic or therapeutic

that register [<sup>F68</sup>; and]

(d) [<sup>F69</sup>in relation to a registered optometrist, the register of optometrists maintained under section 7(a) of the Opticians Act 1989;]

“repeatable prescription” means a prescription which contains a direction that it may be dispensed more than once;

“sell” means sell by retail as defined in section 131 of the Act and “sale” has a corresponding meaning;

“soap” means any compound of a fatty acid with an alkali or amine;

[<sup>F5</sup>“Special Health Authority”—

(a) in relation to England and Wales, has the same meaning as in the National Health Service Act 1977;

(b) in relation to Scotland, means a Special Health Board constituted under section 2 of the National Health Service (Scotland) Act 1978; and

(c) in relation to Northern Ireland, means a Special Health and Social Services Agency established under the Health and Personal Social Services (Special Agencies) (Northern Ireland) Order 1990;]

<sup>F70</sup> ...

<sup>F70</sup> ...

[<sup>F71</sup>“Strategic Health Authority” means a Strategic Health Authority established under section 8 of the National Health Service Act 1977;]

[<sup>F72</sup>“supplementary prescriber” means—

(a) a [<sup>F73</sup>registered] nurse, <sup>F74</sup> ...

(b) a pharmacist, <sup>F75</sup>[<sup>F76</sup> ...

(c) a registered midwife,]<sup>F77</sup> ...

(d) [<sup>F78</sup>a person whose name is registered in the part of the register maintained by the Health Professions Council in pursuance of article 5 of the Health Professions Order 2001 relating to—

(i) chiropodists and podiatrists;

(ii) physiotherapists; or

(iii) radiographers diagnostic or therapeutic [<sup>F79</sup>or]]

(e) [<sup>F80</sup>a registered optometrist, ]

against whose name is recorded in the relevant register an annotation [<sup>F81</sup>or entry] signifying that he is qualified to order drugs, medicines and appliances as a supplementary prescriber [<sup>F82</sup>or, in the case of a nurse or midwife, as a nurse independent/supplementary prescriber]; ]

“supply” means supply in circumstances corresponding to retail sale as defined in section 131 of the Act;

“unit preparation” means a preparation, including a mother tincture, prepared by a process of solution, extraction or trituration with a view to being diluted tenfold or one hundredfold, either once or repeatedly, in an inert diluent, and then used either in this diluted form or, where applicable, by impregnating tablets, granules, powders or other inert substances.

*Status: Point in time view as at 17/01/2011.*

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[<sup>F5</sup>“United Kingdom marketing authorization” means a marketing authorization granted by the licensing authority under the Medicines For Human Use (Marketing Authorisations Etc.) Regulations 1994 (including a product licence having effect as such an authorization by virtue of Schedule 6 to those Regulations [<sup>F83</sup>or an authorization granted by the licensing authority in accordance with Article 126a of Directive 2001/83/EC].]

[<sup>F84</sup>(2A) In paragraph (2), for the purposes of the definition of “independent medical agency”, “undertaking” includes any business or profession and—

- (a) in relation to a public or local authority, includes the exercise of any functions of that authority; and
- (b) in relation to any other body of persons, whether corporate or unincorporate, includes any of the activities of that body.]

(3) For the purposes of this Order, the equivalence of a substance to a reference material shall be determined by calculating the amount of that reference material which is contained in that substance either by weight or, where the amount of the reference material is specified in terms of international units of activity, those units.

(4) In this Order, unless the context otherwise requires, a reference—

- (a) to a numbered section is to the section of the Act which bears that number,
- (b) to a numbered article or Schedule is to the article of, or Schedule to, this Order which bears that number,
- (c) in an article or in a Part of a Schedule to a numbered paragraph is to the paragraph of that article or Part of that Schedule which bears that number, and
- (d) in a paragraph to a lettered sub-paragraph is to the sub-paragraph of that paragraph which bears that letter.

(5) In [<sup>F85</sup>Schedules 1, 2, 3A and 5]—

- (a) entries specified in columns 2 to 5 relate to the substances listed in column 1 against which they appear and where, in relation to a particular substance listed in column 1, an entry in columns 2 to 5 bears a number or letter it relates only to such entries in the other of those columns as bear the same number or letter;
- (b) the following abbreviations are used:

- “g” for gram,
- “iu” for international unit of activity,
- “mcg” for microgram,
- “mg” for milligram,
- “ml” for millilitre.

(6) In Schedule 3, the abbreviation “NPF” means the Nurse Prescribers' Formulary Appendix in the British National Formulary.

[<sup>F86</sup>(7) In articles 12 to [<sup>F87</sup>12E], a reference to a prescription only medicine being sold or supplied for the purpose of being administered in accordance with the written directions of a doctor or dentist relating to a particular person, or in accordance with a Patient Group Direction, includes a reference to it being sold or supplied in accordance with such directions or such a Direction.

(8) In articles 12A and 12C, a reference to an arrangement for the [<sup>F88</sup>sale,] supply or administration of prescription only medicines includes a reference to an arrangement which covers such [<sup>F89</sup>sale,] supply or administration and other matters.

(9) In Schedule 7, Part I, a reference to treatment of a clinical situation includes a reference to any form of management of that situation.]]

### Textual Amendments

- F1** Words in art. 1(2) inserted (30.6.2005) by The Medicines for Human Use (Prescribing) (Miscellaneous Amendments) Order 2005 (S.I. 2005/1507), arts. 1(1), **3(a)**
- F2** Words in art. 1(2) inserted (4.4.2003) by The Prescription Only Medicines (Human Use) Amendment Order 2003 (S.I. 2003/696), arts. 1(1), **2(2)(a)**
- F3** Words in art. 1(2) substituted (1.5.2004) by The Medicines for Human Use (Clinical Trials) Regulations 2004 (S.I. 2004/1031), reg. 1, **Sch. 10 Pt. 2 para. 13(a)**
- F4** Words in art. 1 omitted (1.4.2002) by virtue of The Prescription Only Medicines (Human Use) Amendment Order 2002 (S.I. 2002/549), arts. 1(1), **2(2)(a)**
- F5** Words in art. 1(2) inserted (9.8.2000) by The Prescription Only Medicines (Human Use) Amendment Order 2000 (S.I. 2000/1917), arts. 1(1), **2(a)**
- F6** Words in art. 1(2) inserted (20.11.2005) by The Medicines (Marketing Authorisations Etc.) Amendment Regulations 2005 (S.I. 2005/2759), reg. 1(b), **Sch. para. 5(a)**
- F7** Words in art. 1(2) inserted (1.5.2006) by The Medicines for Human Use (Prescribing) (Miscellaneous Amendments) Order 2006 (S.I. 2006/915), arts. 1(1), **2(a)**
- F8** Words in art. 1(2) inserted (1.6.2010) by The Medicines for Human Use (Miscellaneous Amendments) Order 2010 (S.I. 2010/1136), arts. 1(1), **3(2)**
- F9** Words in art. 1(2) omitted (1.5.2006) by virtue of The Medicines for Human Use (Prescribing) (Miscellaneous Amendments) Order 2006 (S.I. 2006/915), arts. 1(1), **2(b)**
- F10** Words in art. 1(2) omitted (1.5.2006) by virtue of The Medicines for Human Use (Prescribing) (Miscellaneous Amendments) Order 2006 (S.I. 2006/915), arts. 1(1), **2(c)**
- F11** Words in art. 1(2) omitted (1.5.2006) by virtue of The Medicines for Human Use (Prescribing) (Miscellaneous Amendments) Order 2006 (S.I. 2006/915), arts. 1(1), **2(d)**
- F12** Words in art. 1(2) omitted (1.5.2006) by virtue of The Medicines for Human Use (Prescribing) (Miscellaneous Amendments) Order 2006 (S.I. 2006/915), arts. 1(1), **2(e)**
- F13** Words in art. 1(2) repealed (8.5.2009) by The Medicines for Human Use (Prescribing) (Miscellaneous Amendments) Order 2009 (S.I. 2009/1165), arts. 1, 2
- F14** Words in art. 1(2) inserted (4.4.2003) by The Prescription Only Medicines (Human Use) Amendment Order 2003 (S.I. 2003/696), arts. 1(1), **2(2)(d)**
- F15** Words in art. 1(2) inserted (4.4.2003) by The Prescription Only Medicines (Human Use) Amendment Order 2003 (S.I. 2003/696), arts. 1(1), **2(2)(e)**
- F16** Words in art. 1(2) substituted (1.5.2006) by The Medicines for Human Use (Prescribing) (Miscellaneous Amendments) Order 2006 (S.I. 2006/915), arts. 1(1), **2(f)**
- F17** Words in art. 1(2) inserted (4.4.2003) by The Prescription Only Medicines (Human Use) Amendment Order 2003 (S.I. 2003/696), arts. 1(1), **2(2)(f)**
- F18** Words in art. 1(2) inserted (4.4.2003) by The Prescription Only Medicines (Human Use) Amendment Order 2003 (S.I. 2003/696), arts. 1(1), **2(2)(g)**
- F19** Words in art. 1(2) substituted (1.10.2010) by The Health and Social Care Act 2008 (Miscellaneous Consequential Amendments) Order 2010 (S.I. 2010/1881), arts. 1(1), **9(2)(a)**
- F20** Words in art. 1(2) substituted (1.9.2007) by The Medicines for Human Use (Administration and Sale or Supply) (Miscellaneous Amendments) Order 2007 (S.I. 2007/2178), arts. 1(1), **2(2)(a)(i)**
- F21** Words in art. 1(2) inserted (1.9.2007) by The Medicines for Human Use (Administration and Sale or Supply) (Miscellaneous Amendments) Order 2007 (S.I. 2007/2178), arts. 1(1), **2(2)(a)(ii)**
- F22** Words in art. 1(2) substituted (1.10.2010) by The Health and Social Care Act 2008 (Miscellaneous Consequential Amendments) Order 2010 (S.I. 2010/1881), arts. 1(1), **9(2)(b)**
- F23** Words in art. 1(2) substituted (1.9.2007) by The Medicines for Human Use (Administration and Sale or Supply) (Miscellaneous Amendments) Order 2007 (S.I. 2007/2178), arts. 1(1), **2(2)(b)(i)**
- F24** Words in art. 1(2) inserted (1.9.2007) by The Medicines for Human Use (Administration and Sale or Supply) (Miscellaneous Amendments) Order 2007 (S.I. 2007/2178), arts. 1(1), **2(2)(b)(ii)**

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*Changes to legislation: There are currently no known outstanding effects for the The Prescription Only Medicines (Human Use) Order 1997. (See end of Document for details)*

- F25** Words in art. 1(2) substituted (1.10.2010) by The Health and Social Care Act 2008 (Miscellaneous Consequential Amendments) Order 2010 (S.I. 2010/1881), arts. 1(1), **9(2)(c)**
- F26** Words in art. 1(2) substituted (1.9.2007) by The Medicines for Human Use (Administration and Sale or Supply) (Miscellaneous Amendments) Order 2007 (S.I. 2007/2178), arts. 1(1), **2(2)(c)(i)**
- F27** Words in art. 1(2) inserted (1.9.2007) by The Medicines for Human Use (Administration and Sale or Supply) (Miscellaneous Amendments) Order 2007 (S.I. 2007/2178), arts. 1(1), **2(2)(c)(ii)**
- F28** Words in art. 1(2) inserted (17.11.2006) by The Medicines for Human Use (Administration and Sale or Supply) (Miscellaneous Amendments) Order 2006 (S.I. 2006/2807), arts. 1(1), **2(a)**
- F29** Words in art. 1(2) inserted (19.11.2004) by The Prescription Only Medicines (Human Use) Amendment (No. 3) Order 2004 (S.I. 2004/2693), arts. 1(1), **2**
- F30** Words in art. 1(2) inserted (17.11.2006) by The Medicines for Human Use (Administration and Sale or Supply) (Miscellaneous Amendments) Order 2006 (S.I. 2006/2807), arts. 1(1), **2(b)**
- F31** Words in art. 1(2) omitted (17.11.2006) by virtue of The Medicines for Human Use (Administration and Sale or Supply) (Miscellaneous Amendments) Order 2006 (S.I. 2006/2807), arts. 1(1), **2(c)**
- F32** Words in art. 1(2) inserted (1.5.2006) by The Medicines for Human Use (Prescribing) (Miscellaneous Amendments) Order 2006 (S.I. 2006/915), arts. 1(1), **2(g)**
- F33** Words in art. 1(2) inserted (1.4.2004) by The Health and Social Care (Community Health and Standards) Act 2003 (Supplementary and Consequential Provision) (NHS Foundation Trusts) Order 2004 (S.I. 2004/696), arts. 1(1)(b), 3(8), **Sch. 8**
- F34** Words in art. 1(2) inserted (4.4.2003) by The Prescription Only Medicines (Human Use) Amendment Order 2003 (S.I. 2003/696), arts. 1(1), **2(2)(h)**
- F35** Words in art. 1(2) substituted (1.9.2007) by The Medicines for Human Use (Administration and Sale or Supply) (Miscellaneous Amendments) Order 2007 (S.I. 2007/2178), arts. 1(1), **2(2)(d)**
- F36** Words in art. 1(2) substituted (17.11.2006) by The Medicines for Human Use (Administration and Sale or Supply) (Miscellaneous Amendments) Order 2006 (S.I. 2006/2807), arts. 1(1), **2(d)**
- F37** Words in art. 1(2) inserted (4.6.2008) by The Medicines for Human Use (Prescribing) (Miscellaneous Amendments) Order 2008 (S.I. 2008/1161), arts. 1(1), **2**
- F38** Words in art. 1(2) inserted (1.9.2007) by The Medicines for Human Use (Administration and Sale or Supply) (Miscellaneous Amendments) Order 2007 (S.I. 2007/2178), arts. 1(1), **2(2)(e)(i)(aa)**
- F39** Words in art. 1 substituted (10.12.2003) by The Prescription Only Medicines (Human Use) Amendment (No. 2) Order 2003 (S.I. 2003/2915), arts. 1(1), **2**
- F40** Words in art. 1(2) substituted (1.9.2007) by The Medicines for Human Use (Administration and Sale or Supply) (Miscellaneous Amendments) Order 2007 (S.I. 2007/2178), arts. 1(1), **2(2)(e)(i)(bb)**
- F41** Words in art. 1(2) inserted (1.9.2007) by The Medicines for Human Use (Administration and Sale or Supply) (Miscellaneous Amendments) Order 2007 (S.I. 2007/2178), arts. 1(1), **2(2)(e)(ii)**
- F42** Words in art. 1(2) inserted (1.5.2006) by The Medicines for Human Use (Prescribing) (Miscellaneous Amendments) Order 2006 (S.I. 2006/915), arts. 1(1), **2(h)**
- F43** Words in art. 1(2) inserted (4.4.2003) by The Prescription Only Medicines (Human Use) Amendment Order 2003 (S.I. 2003/696), arts. 1(1), **2(2)(i)**
- F44** Words in art. 1 inserted (1.4.2002) by The Prescription Only Medicines (Human Use) Amendment Order 2002 (S.I. 2002/549), arts. 1(1), **2(2)(e)**
- F45** Words in art. 1(2) substituted (1.8.2004) by The Health Act 1999 (Consequential Amendments) (Nursing and Midwifery) Order 2004 (S.I. 2004/1771), art. 1(1), **Sch. para. 39(a)(iv)**
- F46** Words in art. 1(2) inserted (17.11.2006) by The Medicines for Human Use (Administration and Sale or Supply) (Miscellaneous Amendments) Order 2006 (S.I. 2006/2807), arts. 1(1), **2(e)**
- F47** Words in art. 1 inserted (9.7.2003) by The Health Professions Order 2001 (Consequential Amendments) Order 2003 (S.I. 2003/1590), art. 1, **Sch. para. 21(2)(a)**
- F48** Words in art. 1(2) inserted (18.5.2004) by The Prescription Only Medicines (Human Use) Amendment (No. 2) Order 2004 (S.I. 2004/1189), arts. 1(1), **2**
- F49** Words in art. 1(2) substituted (1.8.2004) by The Health Act 1999 (Consequential Amendments) (Nursing and Midwifery) Order 2004 (S.I. 2004/1771), art. 1(1), **Sch. para. 39(a)(v)**
- F50** Words in art. 1(2) substituted (1.8.2004) by The Health Act 1999 (Consequential Amendments) (Nursing and Midwifery) Order 2004 (S.I. 2004/1771), art. 1(1), **Sch. para. 39(a)(vi)**

- F51** Words in art. 1(2) inserted (1.5.2006) by The Medicines for Human Use (Prescribing) (Miscellaneous Amendments) Order 2006 (S.I. 2006/915), arts. 1(1), **2(i)**
- F52** Words in art. 1(2) substituted (3.12.2007) by The European Qualifications (Health and Social Care Professions) Regulations 2007 (S.I. 2007/3101), regs. 1(2), **197**
- F53** Words in art. 1(2) inserted (4.4.2003) by The Prescription Only Medicines (Human Use) Amendment Order 2003 (S.I. 2003/696), arts. 1(1), **2(2)(j)**
- F54** Words in art. 1(2) inserted (1.10.2010) by The Health and Social Care Act 2008 (Miscellaneous Consequential Amendments) Order 2010 (S.I. 2010/1881), arts. 1(1), **9(2)(d)(i)**
- F55** Words in art. 1(2) substituted (1.10.2010) by The Health and Social Care Act 2008 (Miscellaneous Consequential Amendments) Order 2010 (S.I. 2010/1881), arts. 1(1), **9(2)(d)(ii)**
- F56** Words in art. 1(2) inserted (1.9.2007) by The Medicines for Human Use (Administration and Sale or Supply) (Miscellaneous Amendments) Order 2007 (S.I. 2007/2178), arts. 1(1), **2(2)(f)(i)**
- F57** Words in art. 1(2) substituted (1.9.2007) by The Medicines for Human Use (Administration and Sale or Supply) (Miscellaneous Amendments) Order 2007 (S.I. 2007/2178), arts. 1(1), **2(2)(f)(ii)**
- F58** Words in art. 1(2) inserted (1.10.2010) by The Health and Social Care Act 2008 (Miscellaneous Consequential Amendments) Order 2010 (S.I. 2010/1881), arts. 1(1), **9(2)(e)(i)**
- F59** Words in art. 1(2) substituted (1.10.2010) by The Health and Social Care Act 2008 (Miscellaneous Consequential Amendments) Order 2010 (S.I. 2010/1881), arts. 1(1), **9(2)(e)(ii)**
- F60** Words in art. 1(2) inserted (1.9.2007) by The Medicines for Human Use (Administration and Sale or Supply) (Miscellaneous Amendments) Order 2007 (S.I. 2007/2178), arts. 1(1), **2(2)(g)(i)**
- F61** Words in art. 1(2) substituted (1.9.2007) by The Medicines for Human Use (Administration and Sale or Supply) (Miscellaneous Amendments) Order 2007 (S.I. 2007/2178), arts. 1(1), **2(2)(g)(ii)**
- F62** Word in art. 1(2) substituted (1.5.2006) by The Medicines for Human Use (Prescribing) (Miscellaneous Amendments) Order 2006 (S.I. 2006/915), arts. 1(1), **2(j)**
- F63** Words in art. 1(2) inserted (1.8.2004) by The Health Act 1999 (Consequential Amendments) (Nursing and Midwifery) Order 2004 (S.I. 2004/1771), art. 1(1), **Sch. para. 39(a)(vii)**
- F64** Word in art. 1(2) omitted (7.4.2005) by virtue of The Medicines for Human Use (Prescribing) Order 2005 (S.I. 2005/765), arts. 1(1), **3(a)(i)**
- F65** Words in art. 1(2) substituted (27.9.2010) by The Pharmacy Order 2010 (S.I. 2010/231), art. 1(5), **Sch. 4 para. 27** (with Sch. 5); S.I. 2010/1621, art. 2(1), Sch.
- F66** Word in art. 1(b) omitted (30.6.2005) by virtue of The Medicines for Human Use (Prescribing) (Miscellaneous Amendments) Order 2005 (S.I. 2005/1507), arts. 1(1), **3(b)(i)**
- F67** Words in art. 1(2) inserted (7.4.2005) by The Medicines for Human Use (Prescribing) Order 2005 (S.I. 2005/765), arts. 1(1), **3(a)(iii)**
- F68** Word in art. 1(c) inserted (30.6.2005) by The Medicines for Human Use (Prescribing) (Miscellaneous Amendments) Order 2005 (S.I. 2005/1507), arts. 1(1), **3(b)(ii)**
- F69** Words inserted (30.6.2005) by The Medicines for Human Use (Prescribing) (Miscellaneous Amendments) Order 2005 (S.I. 2005/1507), arts. 1(1), **3(b)(iii)**
- F70** Words in art. 1 omitted (9.7.2003) by virtue of The Health Professions Order 2001 (Consequential Amendments) Order 2003 (S.I. 2003/1590), art. 1, **Sch. para. 21(2)(b)**
- F71** Words in art. 1(2) inserted (1.10.2002) by The National Health Service Reform and Health Care Professions Act 2002 (Supplementary, Consequential etc. Provisions) Regulations 2002 (S.I. 2002/2469), regs. 1, 7, **Sch. 4**
- F72** Words in art. 1(2) inserted (4.4.2003) by The Prescription Only Medicines (Human Use) Amendment Order 2003 (S.I. 2003/696), arts. 1(1), **2(2)(k)**
- F73** Word in art. 1(2) substituted (1.5.2006) by The Medicines for Human Use (Prescribing) (Miscellaneous Amendments) Order 2006 (S.I. 2006/915), arts. 1(1), **2(k)(i)**
- F74** Word in art. 1(2) omitted (1.8.2004) by virtue of The Health Act 1999 (Consequential Amendments) (Nursing and Midwifery) Order 2004 (S.I. 2004/1771), art. 1(1), **Sch. para. 39(a)(viii)**
- F75** Word in art. 1(2) omitted (7.4.2005) by virtue of The Medicines for Human Use (Prescribing) Order 2005 (S.I. 2005/765), arts. 1(1), **3(b)(i)**
- F76** Words in art. 1(2) inserted (1.8.2004) by The Health Act 1999 (Consequential Amendments) (Nursing and Midwifery) Order 2004 (S.I. 2004/1771), art. 1(1), **Sch. para. 39(a)(viii)**

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- F77** Word in art. 1(2)(c) omitted (30.6.2005) by virtue of The Medicines for Human Use (Prescribing) (Miscellaneous Amendments) Order 2005 (S.I. 2005/1507), arts. 1(1), **3(c)(i)**
- F78** Words in art. 1(2) inserted (7.4.2005) by The Medicines for Human Use (Prescribing) Order 2005 (S.I. 2005/765), arts. 1(1), **3(b)(iii)**
- F79** Word in art. 1(2)(d) inserted (30.6.2005) by The Medicines for Human Use (Prescribing) (Miscellaneous Amendments) Order 2005 (S.I. 2005/1507), arts. 1(1), **3(c)(ii)**
- F80** Art. 1(2)(e) inserted (30.6.2005) by The Medicines for Human Use (Prescribing) (Miscellaneous Amendments) Order 2005 (S.I. 2005/1507), arts. 1(1), **3(c)(iii)**
- F81** Words in art. 1(2) inserted (7.4.2005) by The Medicines for Human Use (Prescribing) Order 2005 (S.I. 2005/765), arts. 1(1), **3(c)**
- F82** Words in art. 1(2) inserted (1.5.2006) by The Medicines for Human Use (Prescribing) (Miscellaneous Amendments) Order 2006 (S.I. 2006/915), arts. 1(1), **2(k)(ii)**
- F83** Words in art. 1(2) inserted (20.11.2005) by The Medicines (Marketing Authorisations Etc.) Amendment Regulations 2005 (S.I. 2005/2759), reg. 1(b), **Sch. para. 5(b)**
- F84** Art. 1(2A) inserted (1.10.2010) by The Health and Social Care Act 2008 (Miscellaneous Consequential Amendments) Order 2010 (S.I. 2010/1881), arts. 1(1), **9(2)(f)**
- F85** Words in art. 1(5) substituted (1.4.2002) by The Prescription Only Medicines (Human Use) Amendment Order 2002 (S.I. 2002/549), arts. 1(1), **2(3)**
- F86** Words in art. 1(7)-(9) inserted (9.8.2000) by The Prescription Only Medicines (Human Use) Amendment Order 2000 (S.I. 2000/1917), arts. 1(1), **2(b)**
- F87** Word in art. 1(7) substituted (4.4.2003) by The Prescription Only Medicines (Human Use) Amendment Order 2003 (S.I. 2003/696), arts. 1(1), **2(3)**
- F88** Word in art. 1(8) inserted (1.9.2007) by The Medicines for Human Use (Administration and Sale or Supply) (Miscellaneous Amendments) Order 2007 (S.I. 2007/2178), arts. 1(1), **2(3)(a)**
- F89** Word in art. 1(8) inserted (1.9.2007) by The Medicines for Human Use (Administration and Sale or Supply) (Miscellaneous Amendments) Order 2007 (S.I. 2007/2178), arts. 1(1), **2(3)(b)**

**Appropriate practitioners**

2. For the purposes of section 58 (medicinal products on prescription only), the following shall be appropriate practitioners—

- (a) in relation to the descriptions and classes of medicinal products specified in article 3, doctors, dentists [<sup>F90</sup>, supplementary prescribers], [<sup>F91</sup>nurse independent prescribers, pharmacist independent prescribers,] veterinary surgeons and veterinary practitioners;
- [<sup>F92</sup>(b) in relation to the descriptions and classes of medicinal products specified in Schedule 3, [<sup>F93</sup>community practitioner nurse prescribers];
- <sup>F94</sup>(c) . . . . .]
- [<sup>F95</sup>(c) in relation to the descriptions and classes of medicinal products specified in article 3, other than medicinal products that are controlled drugs or for parenteral administration or both , optometrist independent prescribers.]
- <sup>F94</sup>(d) . . . . .

- Textual Amendments**
- F90** Words in art. 2(a) inserted (4.4.2003) by The Prescription Only Medicines (Human Use) Amendment Order 2003 (S.I. 2003/696), arts. 1(1), **3**
  - F91** Words in art. 2(a) added (1.4.2008) by The Prescription Only Medicines (Human Use) Amendment Order 2008 (S.I. 2008/464), arts. 1(1), **2(a)**
  - F92** Art. 2(b)(c) substituted for art. 2(b) (1.4.2002) by The Prescription Only Medicines (Human Use) Amendment Order 2002 (S.I. 2002/549), arts. 1(1), **3**

- F93** Words in art. 2(b) substituted (1.5.2006) by The Medicines for Human Use (Prescribing) (Miscellaneous Amendments) Order 2006 (S.I. 2006/915), arts. 1(1), 3(a)
- F94** Art. 2(c)(d) omitted (1.4.2008) by virtue of The Prescription Only Medicines (Human Use) Amendment Order 2008 (S.I. 2008/464), arts. 1(1), 2(b)
- F95** Art. 2(c) inserted (4.6.2008) by The Medicines for Human Use (Prescribing) (Miscellaneous Amendments) Order 2008 (S.I. 2008/1161), arts. 1(1), 3

**[<sup>F96</sup>Medicinal products on prescription only**

3. The following descriptions and classes of medicinal products are specified for the purposes of section 58, namely—

- (a) medicinal products in respect of which a marketing authorization has been granted, which in the marketing authorization are classified as being prescription only medicines;
- (b) medicinal products in respect of which no marketing authorization has been granted consisting of or containing a substance listed in column 1 of Schedule 1;
- (c) medicinal products that are for parenteral administration;
- (d) medicinal products that are controlled drugs unless a marketing authorization has been granted in respect of that medicinal product in which the product is classified as being a pharmacy only or on general sale list medicine;
- (e) cyanogenetic substances, other than preparations for external use;
- (f) medicinal products that on administration emit radiation, or contain or generate any substance which emits radiation, in order that radiation may be used.
- [<sup>F97</sup>(g) medicinal products in respect of which a marketing authorization has been granted consisting of or containing aloxiprin, aspirin or paracetamol in the form of non-effervescent tablets or capsules which in the marketing authorization are classified as being pharmacy only or general sale list medicines.]
- [<sup>F98</sup>(h) medicinal products in respect of which a marketing authorization has been granted consisting of or containing pseudoephedrine salts or ephedrine base or salts in all pharmaceutical forms which in the marketing authorization are classified as being pharmacy only medicines.]]

**Textual Amendments**

- F96** Art. 3 substituted (1.4.2002) by The Prescription Only Medicines (Human Use) Amendment Order 2002 (S.I. 2002/549), arts. 1(1), 4
- F97** Art. 3(g) added (4.4.2003) by The Prescription Only Medicines (Human Use) Amendment Order 2003 (S.I. 2003/696), arts. 1(1), 4
- F98** Art. 3(h) inserted (1.4.2008) by The Prescription Only Medicines (Human Use) Amendment Order 2008 (S.I. 2008/464), arts. 1(1), 3

**Prescribing and administration by nurse independent prescribers**

<sup>F99</sup>**3A.** . . . . .

**Textual Amendments**

- F99** Art. 3A omitted (1.4.2008) by virtue of The Prescription Only Medicines (Human Use) Amendment Order 2008 (S.I. 2008/464), arts. 1(1), 4

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[<sup>F100</sup> **Prescribing and administration by supplementary prescribers**

**3B.**—(1) Subject to paragraph (2), a supplementary prescriber may—

- (a) give a prescription for a medicinal product referred to in article 3; or
- (b) if that medicinal product is for parenteral administration—
  - (i) administer that medicinal product, or
  - (ii) give directions for the administration of that medicinal product,

only where he complies with the conditions as to the cases or circumstances in which he may do so specified in paragraph (3).

[<sup>F101</sup>(2) Paragraph (1) does not apply if the supplementary prescriber is a community practitioner nurse prescriber and the medicinal product prescribed or administered, or in respect of which he gives directions for administration, falls within a description or class of medicinal products specified in Schedule 3.]

(3) The conditions referred to in paragraph (1) are that—

- (a) the supplementary prescriber is acting in accordance with the terms of a clinical management plan which—
  - (i) relates to the patient for whom the product is prescribed or to whom it is, or is to be, administered,
  - (ii) is in effect at the time the prescription or direction is given or, as the case may be, the product is administered, and
  - (iii) includes the particulars specified in Schedule 3B;

<sup>F102</sup>(b) .....

- (c) the supplementary prescriber has access to the health records of the patient to whom the plan relates which are used by any doctor or dentist who is a party to the plan.

**Textual Amendments**

**F100** Arts. 3B, 3C inserted (4.4.2003) by [The Prescription Only Medicines \(Human Use\) Amendment Order 2003 \(S.I. 2003/696\)](#), arts. 1(1), **6**

**F101** Art. 3B(2) substituted (1.4.2008) by [The Prescription Only Medicines \(Human Use\) Amendment Order 2008 \(S.I. 2008/464\)](#), arts. 1(1), **5**

**F102** Art. 3B(3)(b) omitted (7.4.2005) by virtue of [The Medicines for Human Use \(Prescribing\) Order 2005 \(S.I. 2005/765\)](#), arts. 1(1), **4**

**Exemptions from conditions in respect of the cases or circumstances in which a <sup>F103</sup>... supplementary prescriber may administer a medicinal product**

**3C.** The conditions specified by virtue of <sup>F104</sup>... article 3B(3) shall not apply in relation to the administration of a medicinal product by <sup>F105</sup>... a supplementary prescriber where—

- (a) that person is acting in accordance with the directions of another person who is an appropriate practitioner, or
- (b) that administration is exempt from the restriction in section 58(2)(b) (restriction on administration) by virtue of any of the subsequent provisions of this Order.]



**Textual Amendments**

- F100** Arts. 3B, 3C inserted (4.4.2003) by [The Prescription Only Medicines \(Human Use\) Amendment Order 2003 \(S.I. 2003/696\)](#), arts. 1(1), **6**
- F103** Words in art. 3C heading omitted (1.4.2008) by virtue of [The Prescription Only Medicines \(Human Use\) Amendment Order 2008 \(S.I. 2008/464\)](#), arts. 1(1), **6(a)**
- F104** Words in art. 3C omitted (1.4.2008) by virtue of [The Prescription Only Medicines \(Human Use\) Amendment Order 2008 \(S.I. 2008/464\)](#), arts. 1(1), **6(b)(i)**
- F105** Words in art. 3C omitted (1.4.2008) by virtue of [The Prescription Only Medicines \(Human Use\) Amendment Order 2008 \(S.I. 2008/464\)](#), arts. 1(1), **6(b)(ii)**

**Duration of special provisions in relation to new medicinal products**

<sup>F106</sup>4. ....

**Textual Amendments**

- F106** Art. 4 revoked (1.4.2002) by [The Prescription Only Medicines \(Human Use\) Amendment Order 2002 \(S.I. 2002/549\)](#), arts. 1(1), **11**

**Exempt medicinal products**

5.—(1) A medicinal product shall be exempt from the restrictions imposed by section 58(2)(a) (restrictions on sale or supply) if it, or a substance in it, is listed in column 1 of Schedule 1 and there—

- (a) is an entry in column 2, 3, 4 or 5 of that Schedule which contains a condition and that condition is satisfied in accordance with the following provisions of this article; or
- (b) there is more than one such condition which applies where that substance is used in that product and each of those conditions is so satisfied.

(2) Where a maximum strength is specified in column 2 in relation to a substance, a medicinal product which consists of or contains that substance satisfies the condition where the maximum strength of that substance in that medicinal product, or where specified in that column the maximum strength of a medicinal product which contains that substance, does not exceed that specified maximum or, where the medicinal product consists of more than one of the substances sodium fluoride, sodium monofluorophosphate or stannous fluoride combined in a dentifrice, where the maximum strength of that combination of substances in a product does not exceed the equivalent of 0.15 per cent of fluorine.

(3) Where a route of administration is specified in column 3 in relation to a substance, a medicinal product which consists of or contains that substance satisfies the condition where it is sold or supplied for administration only by that route.

(4) Where a use is specified in column 3 in relation to a substance, a medicinal product which consists of or contains that substance satisfies the condition in respect of use where it is sold or supplied only for use—

- (a) where a purpose for which it may be used is so specified, for that purpose;
- (b) where the class of persons in whom it may be used is so specified, in persons of that class<sup>F107</sup>,

provided that, where the entry in column 3 contains a condition to the effect that the product is to be wholly or mainly for use in a specified class of persons, the product satisfies that condition where it is sold or supplied wholly or mainly for use in persons of that class].

*Status: Point in time view as at 17/01/2011.*

*Changes to legislation: There are currently no known outstanding effects for the The Prescription Only Medicines (Human Use) Order 1997. (See end of Document for details)*

(5) Where a pharmaceutical form is specified in column 3 in relation to a substance, a medicinal product which consists of or contains that substance satisfies the condition where it is sold or supplied in that pharmaceutical form.

(6) Where a maximum dose is specified in column 4 in relation to a substance, a medicinal product which consists of or contains that substance satisfies the condition where it is sold or supplied for use at a maximum dose which does not exceed that specified maximum dose.

(7) Subject to paragraph (8), where a maximum daily dose is specified in column 4 in relation to a substance, a medicinal product which consists of or contains that substance satisfies the condition where it is sold or supplied for use at a maximum daily dose which does not exceed that specified maximum daily dose.

(8) A medicinal product which contains more than one of the substances—

Atropine

Atropine Methobromide

Atropine Methonitrate

Atropine Oxide Hydrochloride

Atropine Sulphate

Hyoscine

Hyoscine Butylbromide

Hyoscine Hydrobromide

Hyoscine Methobromide

Hyoscine Methonitrate

Hyoscyamine

Hyoscyamine Hydrobromide

Hyoscyamine Sulphate,

satisfies the condition only where it is sold or supplied for use at a maximum daily dose which does not exceed 1 milligram in total of the alkaloids derived from belladonna, hyoscyamus, stramonium or other solanaceous plant which are contained in that medicinal product.

(9) Where a maximum period of use or a maximum frequency of use is specified in column 4 in relation to a substance, a medicinal product which consists of or contains that substance satisfies the condition where it is sold or supplied for use for a maximum period or frequency, as the case may be, which does not exceed the maximum period of use or the maximum frequency of use which is so specified.

(10) Where a maximum quantity is specified in column 5 in relation to a substance, a medicinal product which consists of or contains that substance satisfies the condition where it, or where so specified in that column, the medicinal product which contains that substance is sold or supplied in a quantity which does not exceed that specified maximum quantity.

(11) In paragraphs (2) to (7) and (9) and (10) a reference to a numbered column is a reference to the column bearing that number in Schedule 1.

#### **Textual Amendments**

**F107** Words in art. 5(4) added (16.11.2000) by [The Prescription Only Medicines \(Human Use\) Amendment \(No. 2\) Order 2000 \(S.I. 2000/2899\)](#), arts. 1(1), 2

[<sup>F108</sup>Exemption for products consisting of or containing aloxiprin, aspirin or paracetamol

5A. A medicinal product falling within article 3(g) shall be exempt from the restrictions imposed by section 58(2) (restrictions on sale, supply and administration) if the quantity of that product sold or supplied to a person at any one time does not exceed 100 tablets or capsules.]

**Textual Amendments**

**F108** Art. 5A inserted (4.4.2003) by [The Prescription Only Medicines \(Human Use\) Amendment Order 2003 \(S.I. 2003/696\)](#), arts. 1(1), 7

[<sup>F109</sup>Exemption for products consisting of or containing pseudoephedrine salts or ephedrine base or salts

5B.—(1) A medicinal product falling within article 3(h) shall be exempt from the restrictions imposed by section 58(2) (restrictions on sale, supply and administration) if the conditions in paragraph (2) are satisfied—

(2) The conditions referred to in this paragraph are that—

- (a) the medicinal product sold or supplied to a person must not be sold or supplied at the same time as another medicinal product that consists of or contains—
  - (i) in the case of pseudoephedrine salts, ephedrine base or salts;
  - (ii) in the case of ephedrine base or salts, pseudoephedrine salts; and
- (b) the medicinal product or products sold or supplied to a person at any one time must not in total contain more than—
  - (i) in the case of pseudoephedrine salts, 720mg pseudoephedrine salts;
  - (ii) in the case of ephedrine base or salts, 180mg ephedrine base or salts. ]

**Textual Amendments**

**F109** Art. 5B inserted (1.4.2008) by [The Prescription Only Medicines \(Human Use\) Amendment Order 2008 \(S.I. 2008/464\)](#), arts. 1(1), 7

**Circumstances in which controlled drugs and medicinal products authorized by the European Community are not prescription only medicines**

<sup>F110</sup>6. ....

**Textual Amendments**

**F110** Art. 6 revoked (1.4.2002) by [The Prescription Only Medicines \(Human Use\) Amendment Order 2002 \(S.I. 2002/549\)](#), arts. 1(1), 11

**Exemption for parenteral administration in an emergency to human beings of certain prescription only medicines**

7. The restriction imposed by section 58(2)(b) (restriction on administration) shall not apply to the administration to human beings of any of the following medicinal products for parenteral administration—

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Adrenaline Injection 1 in 1000 (1 mg in 1 ml)  
 Atropine Sulphate Injection  
 [<sup>F111</sup>Atropine sulphate and obidoxime chloride injection]  
 [<sup>F111</sup>Atropine sulphate and pralidoxime chloride injection]  
 [<sup>F111</sup>Atropine sulphate, pralidoxime mesilate and avizafone injection]  
 [<sup>F112</sup>Chlorphenamine Injection]  
 [<sup>F113</sup>Dicobalt Edetate Injection]  
 F114 ...  
 F114 ...  
 Glucagon Injection  
 [<sup>F115</sup>Glucose Injection]  
 Hydrocortisone Injection  
 [<sup>F116</sup>Naloxone Hydrochloride]  
 [<sup>F111</sup>Pralidoxime chloride injection]  
 [<sup>F111</sup>Pralidoxime mesilate injection]  
 Promethazine Hydrochloride Injection  
 Snake Venom Antiserum  
 Sodium Nitrite Injection  
 Sodium Thiosulphate Injection  
 Sterile Pralidoxime

where the administration is for the purpose of saving life in an emergency.

#### **Textual Amendments**

- F111** Words in [art. 7](#) inserted (19.11.2004) by [The Prescription Only Medicines \(Human Use\) Amendment \(No. 3\) Order 2004 \(S.I. 2004/2693\)](#), arts. 1(1), **3**
- F112** Words in [art. 7](#) substituted (30.6.2005) by [The Medicines for Human Use \(Prescribing\) \(Miscellaneous Amendments\) Order 2005 \(S.I. 2005/1507\)](#), arts. 1(1), **4(a)**
- F113** Words in [art. 7](#) substituted (30.6.2005) by [The Medicines for Human Use \(Prescribing\) \(Miscellaneous Amendments\) Order 2005 \(S.I. 2005/1507\)](#), arts. 1(1), **4(b)**
- F114** Words in [art. 7](#) omitted (30.6.2005) by virtue of [The Medicines for Human Use \(Prescribing\) \(Miscellaneous Amendments\) Order 2005 \(S.I. 2005/1507\)](#), arts. 1(1), **4(c)**
- F115** Words in [art. 7](#) substituted (17.1.2011) by [The Prescription Only Medicines \(Human Use\) Amendment Order 2010 \(S.I. 2010/2998\)](#), arts. 1(1), **2**
- F116** Words in [art. 7](#) substituted (30.6.2005) by [The Medicines for Human Use \(Prescribing\) \(Miscellaneous Amendments\) Order 2005 \(S.I. 2005/1507\)](#), arts. 1(1), **4(e)**

#### **[<sup>F117</sup>Exemptions for administration of smallpox vaccine**

**7A.**—(1) The restriction imposed by section 58(2)(b) (restriction on administration) shall not apply to the administration to human beings of smallpox vaccine where the conditions specified in paragraph (2) or (3) are satisfied.

(2) The conditions referred to in this paragraph are—

- (a) the vaccine has been supplied by, or on behalf of, or under arrangements made by—
  - (i) the Secretary of State,
  - (ii) the Scottish Ministers,
  - (iii) the National Assembly for Wales,
  - (iv) the Department of Health, Social Services and Public Safety,
  - (v) an NHS body; and
- (b) the vaccine is administered for the purpose of providing protection against smallpox virus in the event of a suspected or confirmed case of smallpox in the United Kingdom.
- (3) The conditions referred to in this paragraph are—
  - (a) the vaccine has been supplied by, or on behalf of, or under arrangements made by Her Majesty's Forces;
  - (b) the vaccine is administered for the purpose of providing protection against smallpox virus to—
    - (i) members of Her Majesty's Forces; or
    - (ii) other persons employed or engaged by those Forces.
- (4) For the purposes of this regulation, "NHS body" means—
  - (a) the Common Services Agency,
  - (b) a Strategic Health Authority, Health Authority or Special Health Authority,
  - (c) a Primary Care Trust,
  - (d) a Local Health Board, or
  - (e) an NHS trust or NHS foundation trust]

#### Textual Amendments

**F117** Art. 7A inserted (19.11.2004) by [The Prescription Only Medicines \(Human Use\) Amendment \(No. 3\) Order 2004 \(S.I. 2004/2693\)](#), arts. 1(1), 4

#### **[<sup>F118</sup>Exemption for administration by operators**

**7B.**—(1) The restriction imposed by section 58(2)(b) (restriction on administration) shall not apply to—

- (a) a radioactive medicinal product, administration of which results in a medical exposure; or
- (b) any other prescription only medicine if it is being administered in connection with a medical exposure,

where the conditions specified in paragraph (2) are satisfied.

- (2) The conditions referred to in paragraph (1) are that—
  - (a) the radioactive medicinal product or other prescription only medicine is administered by an operator acting in accordance with the procedures and protocols referred to in regulation 4(1) and (2) of the Ionising Radiation (Medical Exposure) Regulations 2000 which apply to the exposure referred to in paragraph (1);
  - (b) that medical exposure has been authorised by an IRME practitioner or, where it is not practicable for an IRME practitioner to authorise the exposure, by an operator acting in accordance with written guidelines issued by an IRME practitioner;

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- (c) the IRME practitioner is the holder of a certificate granted pursuant to the Medicines (Administration of Radioactive Substances) Regulations 1978(5);
- (d) the radioactive medicinal product or other prescription only medicine is not a controlled drug; and
- (e) in the case of a prescription only medicine which is not a radioactive medicinal product, it is specified in the protocols referred to in sub-paragraph (a).]

#### Textual Amendments

**F118** Art. 7B inserted (17.11.2006) by The Medicines for Human Use (Administration and Sale or Supply) (Miscellaneous Amendments) Order 2006 (S.I. 2006/2807), arts. 1(1), 3

#### Exemptions for emergency sale or supply

8.—(1) The restrictions imposed by section 58(2)(a) (restriction on sale and supply) shall not apply to the sale or supply of a prescription only medicine by a person lawfully conducting a retail pharmacy business where the conditions specified in paragraph (2) are satisfied.

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

- (a) that the pharmacist by or under whose supervision the prescription only medicine is to be sold or supplied is satisfied that the sale or supply has been requested by a doctor [<sup>F119</sup>, a supplementary prescriber][<sup>F120</sup>a community practitioner nurse prescriber, a nurse independent prescriber [<sup>F121</sup>, an optometrist independent prescriber][<sup>F122</sup>, dentist] or a pharmacist independent prescriber] who by reason of an emergency is unable to furnish a prescription immediately;
- (b) that the doctor [<sup>F123</sup>, supplementary prescriber] , [<sup>F124</sup>community practitioner nurse prescriber, nurse independent prescriber [<sup>F125</sup>, optometrist independent prescriber][<sup>F122</sup>, dentist] or pharmacist independent prescriber] has undertaken to furnish the person lawfully conducting a retail pharmacy business with a prescription within 72 hours of the sale or supply;
- (c) that the prescription only medicine is sold or supplied in accordance with the directions of the doctor [<sup>F126</sup>, supplementary prescriber] , [<sup>F127</sup>community practitioner nurse prescriber, nurse independent prescriber [<sup>F128</sup>, optometrist independent prescriber][<sup>F122</sup>, dentist] or pharmacist independent prescriber] requesting it;
- (d) subject to paragraph (5), that the prescription only medicine is not a controlled drug specified in Schedule 1, 2 or 3 to the Misuse of Drugs Regulations;
- (e) that an entry is made in the record kept under regulation 6 of the Medicines (Sale or Supply) (Miscellaneous Provisions) Regulations 1980(12) within the time specified in that regulation stating the particulars required under paragraph 1 of Schedule 2 to those Regulations.

(3) The restrictions imposed by section 58(2)(a) shall not apply to the sale or supply of a prescription only medicine by a person lawfully conducting a retail pharmacy business where the conditions specified in paragraph (4) are satisfied.

(4) The conditions referred to in paragraph (3) are—

(5) 1978 c. 29.

(12) S.I. 1980/1923, amended by S.I. 1997/1831.

- (a) [<sup>F129</sup>subject to paragraph (6)] that the pharmacist by or under whose supervision the prescription only medicine is to be sold or supplied has interviewed the person requesting a prescription only medicine and has satisfied himself—
- (i) that there is an immediate need for the prescription only medicine requested to be sold or supplied and that it is impracticable in the circumstances to obtain a prescription without undue delay,
  - (ii) that treatment with the prescription only medicine requested has on a previous occasion been prescribed by a doctor [<sup>F130</sup>, supplementary prescriber], [<sup>F131</sup>community practitioner nurse prescriber, nurse independent prescriber [<sup>F132</sup>, optometrist independent prescriber][<sup>F133</sup>, dentist] or pharmacist independent prescriber] for the person requesting it, and
  - (iii) as to the dose which in the circumstances it would be appropriate for that person to take;
- (b) that no greater quantity of the prescription only medicine than will provide 5 days' treatment [<sup>F134</sup>in the case of a controlled drug or 30 days in any other case] is sold or supplied except that where the prescription only medicine—
- (i) is [<sup>F135</sup>a preparation of insulin,] an aerosol for the relief of asthma, an ointment or cream, and has been made up for sale in a container elsewhere than at the place of sale or supply, the smallest pack that the pharmacist has available for sale or supply may be sold or supplied,
  - (ii) is an oral contraceptive, a quantity sufficient for a full treatment cycle may be sold or supplied,
  - (iii) is an antibiotic for oral administration in liquid form, the smallest quantity that will provide a full course of treatment may be sold or supplied;
- (c) subject to paragraph (5), that the prescription only medicine does not consist of or contain a substance specified in Schedule 4 to this Order and is not a controlled drug specified in Schedule 1, 2 or 3 to the Misuse of Drugs Regulations;
- (d) that an entry is made in the record kept under regulation 6 of the Medicines (Sale or Supply) (Miscellaneous Provisions) Regulations 1980 within the time specified in that regulation stating the particulars required under paragraph 3 of Schedule 2 to those Regulations;
- (e) that the container or package of the prescription only medicine is labelled so as to show—
- (i) the date on which the prescription only medicine is sold or supplied,
  - (ii) the name, quantity and, except where it is apparent from the name, the pharmaceutical form and strength of the prescription only medicine,
  - (iii) the name of the person requesting the prescription only medicine,
  - (iv) the name and address of the registered pharmacy from which the prescription only medicine is sold or supplied, and
  - (v) the words “Emergency Supply”.

(5) The conditions specified in paragraphs (2)(d) and (4)(c) shall not apply where the prescription only medicine consists of or contains phenobarbitone or phenobarbitone sodium (but no other substance specified in Schedule 4 to this Order or Schedule 1, 2 or 3 to the Misuse of Drugs Regulations) and is sold or supplied for use in the treatment of epilepsy.

[<sup>F136</sup>(6) Paragraph (4)(a) does not apply in relation to the sale or supply of a prescription only medicine where—

- (a) the sale or supply is made—
  - (i) whilst a disease is, or

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- (ii) in anticipation of a disease being imminently, pandemic and a serious risk, or potentially a serious risk, to human health; and
- (b) the pharmacist by or under whose supervision the prescription only medicine is to be sold or supplied has satisfied himself—
  - (i) that treatment with the prescription only medicine requested has on a previous occasion been prescribed by a doctor, supplementary prescriber, community practitioner nurse prescriber, nurse independent prescriber, optometrist independent prescriber or pharmacist independent prescriber for the person to be treated with it; and
  - (ii) as to the dose which in the circumstances it would be appropriate for that person to take.]

### Textual Amendments

- F119** Words in art. 8(2)(a) inserted (4.4.2003) by The Prescription Only Medicines (Human Use) Amendment Order 2003 (S.I. 2003/696), arts. 1(1), **8(a)(i)**
- F120** Words in art. 8(2)(a) substituted (1.5.2006) by The Medicines for Human Use (Prescribing) (Miscellaneous Amendments) Order 2006 (S.I. 2006/915), arts. 1(1), **7(a)(i)**
- F121** Words in art. 8(2)(a) inserted (4.6.2008) by The Medicines for Human Use (Prescribing) (Miscellaneous Amendments) Order 2008 (S.I. 2008/1161), arts. 1(1), **4(a)(i)**
- F122** Word in art. 8(2) inserted (8.5.2009) by The Medicines for Human Use (Prescribing)(Miscellaneous Amendments) Order 2009 (S.I. 2009/1165), arts. 1, **3(a)**
- F123** Words in art. 8(2)(b) inserted (4.4.2003) by The Prescription Only Medicines (Human Use) Amendment Order 2003 (S.I. 2003/696), arts. 1(1), **8(a)(ii)**
- F124** Words in art. 8(2)(b) substituted (1.5.2006) by The Medicines for Human Use (Prescribing) (Miscellaneous Amendments) Order 2006 (S.I. 2006/915), arts. 1(1), **7(a)(ii)**
- F125** Words in art. 8(2)(b) inserted (4.6.2008) by The Medicines for Human Use (Prescribing) (Miscellaneous Amendments) Order 2008 (S.I. 2008/1161), arts. 1(1), **4(a)(ii)**
- F126** Words in art. 8(2)(c) inserted (4.4.2003) by The Prescription Only Medicines (Human Use) Amendment Order 2003 (S.I. 2003/696), arts. 1(1), **8(a)(iii)**
- F127** Words in art. 8(2)(c) substituted (1.5.2006) by The Medicines for Human Use (Prescribing) (Miscellaneous Amendments) Order 2006 (S.I. 2006/915), arts. 1(1), **7(a)(iii)**
- F128** Words in art. 8(2)(c) inserted (4.6.2008) by The Medicines for Human Use (Prescribing) (Miscellaneous Amendments) Order 2008 (S.I. 2008/1161), arts. 1(1), **4(a)(iii)**
- F129** Words in art. 8(4)(a) inserted (8.5.2009) by The Medicines for Human Use (Prescribing) (Miscellaneous Amendments) Order 2009 (S.I. 2009/1165), arts. 1, **3(b)(i)**
- F130** Words in art. 8(4)(a)(ii) inserted (4.4.2003) by The Prescription Only Medicines (Human Use) Amendment Order 2003 (S.I. 2003/696), arts. 1(1), **8(b)**
- F131** Words in art. 8(4)(a)(ii) substituted (1.5.2006) by The Medicines for Human Use (Prescribing) (Miscellaneous Amendments) Order 2006 (S.I. 2006/915), arts. 1(1), **7(b)**
- F132** Words in art. 8(4)(a)(ii) inserted (4.6.2008) by The Medicines for Human Use (Prescribing) (Miscellaneous Amendments) Order 2008 (S.I. 2008/1161), arts. 1(1), **4(b)**
- F133** Word in art. 8(4)(a)(ii) inserted (8.5.2009) by The Medicines for Human Use (Prescribing) (Miscellaneous Amendments) Order 2009 (S.I. 2009/1165), arts. 1, **3(b)(ii)**
- F134** Words in art. 8(4)(b) inserted (8.5.2009) by The Medicines for Human Use (Prescribing) (Miscellaneous Amendments) Order 2009 (S.I. 2009/1165), arts. 1, **3(c)**
- F135** Words in art. 8(4)(b)(i) inserted (16.9.1998) by The Prescription Only Medicines (Human Use) Amendment (No. 3) Order 1998 (S.I. 1998/2081), arts. 1(1), **2**
- F136** Art. 8(6) inserted (8.5.2009) by The Medicines for Human Use (Prescribing)(Miscellaneous Amendments) Order 2009 (S.I. 2009/1165), arts. 1, **3(d)**



### Exemption for non-parenteral administration to human beings

9. The restriction imposed by section 58(2)(b) (restriction on administration) shall not apply to the administration to human beings of a prescription only medicine which is not for parenteral administration.

### Exemption for medicinal products at high dilutions

10.—<sup>F137</sup>(1) The restrictions imposed by section 58(2) (restrictions on sale, supply and administration) shall not apply to the sale, supply or administration of a medicinal product which is not for parenteral administration and which consists of or contains, any of the substances listed in column 1 of Schedule 1 <sup>F138</sup>or in Schedule 2], only one or more unit preparation of such substances, if—

- (a) each such unit preparation has been diluted to at least one part in a million (6x), and the person selling, supplying or administering the medicinal product has been requested by or on behalf of a particular person and in that person's presence to use his own judgment as to the treatment required; or
- (b) each such unit preparation has been diluted to at least one part in a million million (6c).

<sup>F139</sup>(2) The restrictions imposed by section 58(2) (restrictions on sale, supply and administration) shall not apply to the sale, supply or administration of a medicinal product which is not for parenteral administration and which consists of or contains solely one or more unit preparations of the following substances—

Aconite  
Arsenic Trioxide  
Belladonna Herb  
Ignatia Bean  
Nux Vomica Seed,

if each such unit preparation has been diluted to at least one part in a million (6x)]

#### Textual Amendments

**F137** Art. 10 renumbered as art. 10(1) (4.4.2003) by The Prescription Only Medicines (Human Use) Amendment Order 2003 (S.I. 2003/696), arts. 1(1), 9

**F138** Words in art. 10(1) substituted (1.5.2006) by The Medicines for Human Use (Prescribing) (Miscellaneous Amendments) Order 2006 (S.I. 2006/915), arts. 1(1), 8

**F139** Art. 10(2) inserted (4.4.2003) by The Prescription Only Medicines (Human Use) Amendment Order 2003 (S.I. 2003/696), arts. 1(1), 9

### Exemptions for certain persons

11.—(1) The restrictions imposed by section 58(2)(a) (restrictions on sale and supply) shall not apply—

- (a) to the sale or supply by a person listed in column 1 of Part I of Schedule 5 of the prescription only medicines listed in relation to that person in column 2 of that Part where the conditions specified in the corresponding paragraphs in column 3 of that Part are satisfied;
- (b) to the supply by a person listed in column 1 of Part II of Schedule 5 of the prescription only medicines listed in relation to that person in column 2 of that Part where the conditions specified in the corresponding paragraphs in column 3 of that Part are satisfied.

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*Changes to legislation: There are currently no known outstanding effects for the The Prescription Only Medicines (Human Use) Order 1997. (See end of Document for details)*

(2) The restriction imposed by section 58(2)(b) (restriction on administration) shall not apply to the administration by a person listed in column 1 of Part III of Schedule 5 of the prescription only medicines for parenteral administration listed in relation to that person in column 2 of that Part where the conditions specified in the corresponding paragraphs in column 3 of that Part are satisfied.

#### **[<sup>F140</sup>Exemption for sale or supply in hospitals**

**12.**—(1) Subject to paragraph (3), the restrictions imposed by section 58(2)(a) (restrictions on sale and supply) shall not apply to the sale or supply of a prescription only medicine in the course of the business of a hospital where the medicine is sold or supplied for the purpose of being administered (whether in the hospital or elsewhere) to a particular person in accordance with directions satisfying the conditions specified in paragraph (2).

(2) The conditions specified in paragraph (1) are that the directions—

- (a) are in writing;
- (b) relate to the particular person to whom the medicine is to be administered; and
- (c) are given by a person (other than a veterinary surgeon or veterinary practitioner) who is an appropriate practitioner in relation to that medicine.

(3) Such directions may be given by <sup>F141</sup>... a supplementary prescriber only where he complies with any condition as to the cases or circumstances in which he may give a prescription for that medicine specified by virtue of article <sup>F142</sup>... 3B, as if the directions are a prescription.

(4) The exemption in paragraph (1) applies notwithstanding that the directions do not satisfy the conditions specified in article 15(2).]

#### **Textual Amendments**

**F140** Art. 12 substituted (31.1.2004) by [The Prescription Only Medicines \(Human Use\) Amendment Order 2004 \(S.I. 2004/2\)](#), arts. 1(1), **2**

**F141** Words in art. 12(3) omitted (1.4.2008) by virtue of [The Prescription Only Medicines \(Human Use\) Amendment Order 2008 \(S.I. 2008/464\)](#), arts. 1(1), **8(a)**

**F142** Words in art. 12(3) omitted (1.4.2008) by virtue of [The Prescription Only Medicines \(Human Use\) Amendment Order 2008 \(S.I. 2008/464\)](#), arts. 1(1), **8(b)**

#### **[<sup>F143</sup>Exemptions for the supply and administration of prescription only medicines by national health service bodies**

**12A.**—(1) The restrictions imposed by section 58(2)(a) (restrictions on sale and supply) shall not apply to the supply of a prescription only medicine by—

- (a) the Common Services Agency;
- (b) a [<sup>F144</sup>Strategic Health Authority,] Health Authority or Special Health Authority;
- (c) an NHS trust [<sup>F145</sup>or NHS foundation trust];
- (d) a Primary Care Trust; or
- (e) where sub-paragraphs (a) to (d) do not apply, a person other than an excepted person, pursuant to an arrangement made with one of the persons specified in those sub-paragraphs for the supply of prescription only medicines,

where the medicine is supplied for the purpose of being administered to a particular person in accordance with the written directions of a doctor or dentist relating to that person notwithstanding that those directions do not satisfy the conditions specified in article 15(2).

(2) The restrictions imposed by section 58(2) (restrictions on sale, supply and administration) shall not apply to the supply or, as the case may be, the administration of a prescription only medicine by—

- (a) the Common Services Agency;
- (b) a [<sup>F146</sup>Strategic Health Authority,] Health Authority or Special Health Authority;
- (c) an NHS trust [<sup>F147</sup>or NHS foundation trust];
- (d) a Primary Care Trust; or
- (e) where sub-paragraphs (a) to (d) do not apply, a person other than an excepted person, pursuant to an arrangement made with one of the persons specified in those sub-paragraphs for the supply or, as the case may be, the administration of prescription only medicines,

where the medicine is supplied for the purpose of being administered, or, as the case may be, is administered, to a particular person in accordance with a Patient Group Direction and where the conditions specified in paragraph (3) are satisfied.

(3) The conditions referred to are that—

- (a) the Patient Group Direction relates to the supply or, as the case may be, the administration, by the person who supplies or administers the medicine, of a description or class of prescription only medicine, and the Direction has effect at the time at which the medicine is supplied or, as the case may be, is administered;
- (b) the Patient Group Direction contains the particulars specified in Part I of Schedule 7 to this Order (but with the omission of paragraph (c) of that Part in the case of a Direction which relates to administration only);
- (c) the Patient Group Direction is signed on behalf of the person specified in column 2 of the Table in Part II of Schedule 7 to this Order (“the authorising person”) against the entry in column 1 of that Table for the class of person by whom the medicine is supplied or administered;
- (d) the individual who supplies or, as the case may be, administers the medicine belongs to one of the classes of individual specified in Part III of Schedule 7 to this Order, and is designated in writing, on behalf of the authorising person, for the purpose of the supply or, as the case may be, the administration of prescription only medicines under the Patient Group Direction; and
- (e) at the time at which the medicine is supplied or, as the case may be, is administered, a product licence, a marketing authorization or a homoeopathic certificate of registration has effect in respect of it.

(4) In this article, “excepted person” means—

- (a) a doctor or dentist; or
- (b) a person lawfully conducting a retail pharmacy business within the meaning of section 69.

#### Textual Amendments

**F143** Arts. 12A-12C inserted (9.8.2000) by The Prescription Only Medicines (Human Use) Amendment Order 2000 (S.I. 2000/1917), arts. 1(1), 2(d)

**F144** Words in art. 12A(1)(b) inserted (1.10.2002) by The National Health Service Reform and Health Care Professions Act 2002 (Supplementary, Consequential etc. Provisions) Regulations 2002 (S.I. 2002/2469), reg. 1, Sch. 1 para. 73(2)(a)

**F145** Words in art. 12A(1)(c) inserted (1.4.2004) by The Health and Social Care (Community Health and Standards) Act 2003 (Supplementary and Consequential Provision) (NHS Foundation Trusts) Order 2004 (S.I. 2004/696), arts. 1(1)(b), 3(2), Sch. 2

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- F146** Words in art. 12A(2)(b) inserted (1.10.2002) by The National Health Service Reform and Health Care Professions Act 2002 (Supplementary, Consequential etc. Provisions) Regulations 2002 (S.I. 2002/2469), reg. 1, **Sch. 1 para. 73(2)(b)**
- F147** Words in art. 12A(2)(c) inserted (1.4.2004) by The Health and Social Care (Community Health and Standards) Act 2003 (Supplementary and Consequential Provision) (NHS Foundation Trusts) Order 2004 (S.I. 2004/696), arts. 1(1)(b), 3(2), **Sch. 2**

### **Exemption for health professionals who supply or administer prescription only medicines under a Patient Group Direction in order to assist doctors or dentists in providing national health services**

**12B.**—(1) The restrictions imposed by section 58(2) (sale, supply and administration) shall not apply to the supply or, as the case may be, the administration of a prescription only medicine by an individual belonging to one of the classes specified in Part III of Schedule 7 to this Order where—

- (a) the individual supplies or, as the case may be, administers the medicine in order to assist a doctor or dentist in the provision of, respectively, NHS primary medical services or NHS primary dental services;
  - (b) the medicine is supplied for the purpose of being administered, or, as the case may be, is administered, in accordance with a Patient Group Direction; and
  - (c) the conditions specified in paragraph (2) are satisfied.
- (2) The conditions referred to are that—
- (a) the Patient Group Direction relates to the supply or, as the case may be, the administration of a description or class of prescription only medicine in order to assist the doctor or dentist in question in providing the services referred to in paragraph (1)(a) (whether or not it also relates to such supply or administration in order to assist any other doctor or dentist);
  - (b) the Patient Group Direction has effect at the time at which the medicine is supplied or, as the case may be, is administered;
  - (c) the Patient Group Direction contains the particulars specified in Part I of Schedule 7 to this Order (but with the omission of paragraph (c) of that Part in the case of a Direction which relates to administration only);
  - (d) the Patient Group Direction is signed—
    - (i) by the doctor or dentist in question or, alternatively, where the Direction also relates to supply or administration in order to assist one or more other doctors or dentists, as referred to in sub-paragraph (a), by one of those other doctors or dentists; and
    - [<sup>F148</sup>(ii) on behalf of the Primary Care Trust, Local Health Board, Health Board or Health and Social Services Board that is responsible for the arrangements under which the services are provided]
  - (e) the individual referred to in paragraph (1) is designated in writing for the purpose of the supply or, as the case may be, the administration of prescription only medicines under the Patient Group Direction, by the doctor or dentist in question, or, alternatively, where the Direction also relates to supply or administration in order to assist one or more other doctors or dentists, as referred to in sub-paragraph (a), by one of those other doctors or dentists; and
  - (f) at the time at which the medicine is supplied or, as the case may be, is administered, a product licence, a marketing authorization or a homoeopathic certificate of registration has effect in respect of it.
- (3) In this article—

- (a) a reference to the provision of NHS primary dental services shall be construed as a reference to—
- [<sup>F149</sup>(i) in relation to England and Wales, the provision of primary dental services under Part 1 of the National Health Service Act 1977;]
  - (ii) in relation to Scotland, the provision of general dental services under Part II of the National Health Service (Scotland) Act 1978, or the performance of personal dental services in connection with a pilot scheme under the National Health Service (Primary Care) Act 1997; and
  - (iii) in relation to Northern Ireland, the provision of general dental services under the Health and Personal Social Services (Northern Ireland) Order 1972, or the performance of personal dental services in connection with a pilot scheme under the Health Services (Primary Care) (Northern Ireland) Order 1997;
- (b) a reference to the provision of NHS primary medical services shall be construed as a reference to—
- [<sup>F150</sup>(i) in relation to England and Wales, the provision of primary medical services under Part I of the National Health Service Act 1977;]
  - [<sup>F151</sup>(ii) in relation to Scotland, the provision of primary medical services under Part I of the National Health Service (Scotland) Act 1978; and]
  - [<sup>F152</sup>(iii) in relation to Northern Ireland, the provision of primary medical services under Article 15B or Part VI of the Health and Personal Social Services (Northern Ireland) Order 1972.]

#### Textual Amendments

- F143** Arts. 12A-12C inserted (9.8.2000) by The Prescription Only Medicines (Human Use) Amendment Order 2000 (S.I. 2000/1917), arts. 1(1), **2(d)**
- F148** Art. 12B(2)(d)(ii) substituted (1.4.2006) by The General Dental Services, Personal Dental Services and Abolition of the Dental Practice Board Transitional and Consequential Provisions Order 2006 (S.I. 2006/562), art. 1(1), **Sch. 1 para. 6(2)(a)**
- F149** Art. 12B(3)(a)(i) substituted (1.4.2006) by The General Dental Services, Personal Dental Services and Abolition of the Dental Practice Board Transitional and Consequential Provisions Order 2006 (S.I. 2006/562), art. 1(1), **Sch. 1 para. 6(2)(b)**
- F150** Art. 12B(3)(b)(i) substituted (E.) (1.4.2004) by The General Medical Services and Personal Medical Services Transitional and Consequential Provisions Order 2004 (S.I. 2004/865), art. 1(1), **Sch. 1 para. 18(2)**; and substituted (W.) by The General Medical Services Transitional and Consequential Provisions (Wales) (No. 2) Order 2004 (S.I. 2004/1016), art. 1(1), **Sch. 1 para. 18(2)**
- F151** Art. 12B(3)(b)(ii) substituted (1.10.2004) by The Primary Medical Services (Scotland) Act 2004 (Consequential Amendments) Order 2004 (S.I. 2004/2261), art. 1(1), **Sch. para. 2**
- F152** Art. 12B(3)(b)(iii) substituted (18.11.2004) by The Primary Medical Services (Northern Ireland) Order 2004 (Consequential Amendments) Order 2004 (S.I. 2004/3038), art. 1(1), **Sch. para. 3**

#### Exemption for persons conducting a retail pharmacy business who supply or administer prescription only medicines under a Patient Group Direction

**12C.—(1)** The restrictions imposed by section 58(2) (restrictions on sale, supply and administration) shall not apply to the [<sup>F153</sup>sale or] supply or, as the case may be, the administration of a prescription only medicine by a person lawfully conducting a retail pharmacy business within the meaning of section 69 where—

- [<sup>F154</sup>(a) the medicine—

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- (i) is supplied, or as the case may be, is administered by such a person pursuant to an arrangement made with—
  - (aa) a body referred to in article 12A(a) to (d),
  - (bb) a force or service referred to in article 12E(1)(a)(i) to (iii), or
  - (cc) Her Majesty’s Forces,
 for the supply or, as the case may be, the administration of prescription only medicines; or
- (ii) is sold or supplied or, as the case may be, is administered by such a person pursuant to an arrangement made with an authority or person carrying on the business of an establishment or agency referred to in article 12D(1) for the sale or supply or, as the case may be, the administration of prescription only medicines;]
- (b) the medicine is [<sup>F155</sup>sold or] supplied for the purpose of being administered, or, as the case may be, is administered, to a particular person in accordance with a Patient Group Direction; and
- (c) the conditions specified in paragraph (2) are satisfied.
- (2) The conditions referred to are that—
  - (a) the Patient Group Direction relates to the [<sup>F156</sup>sale or] supply or, as the case may be, the administration of a description or class of prescription only medicine by the person lawfully conducting a retail pharmacy business who [<sup>F157</sup>sells or] supplies or, as the case may be, administers the prescription only medicine, and the Direction has effect at the time at which the medicine is [<sup>F158</sup>sold or] supplied or, as the case may be, is administered;
  - (b) the Patient Group Direction contains the particulars specified in Part I of Schedule 7 to this Order (but with the omission of paragraph (c) of that Part in the case of a Direction which relates to administration only);
  - [<sup>F159</sup>(c) the Patient Group Direction is signed—
    - (i) in the case of an arrangement with a body referred to in article 12A(a) to (d), on behalf of that body,
    - (ii) in the case of an arrangement with an authority or person carrying on the business of an establishment or agency referred to in article 12D(1), by or on behalf of the relevant provider and, if there is a relevant manager for the establishment or agency, that manager,
    - (iii) in the case of an arrangement with a prison service, by or on behalf of the person specified in column 2 of the Table in Part IIA of Schedule 7 to this Order against the entry in column 1 of that Table for that service,
    - (iv) in the case of an arrangement with a police force or the Police Service of Northern Ireland—
      - (a) by or on behalf of the person specified in column 2 of the Table in Part IIA of Schedule 7 to this Order against the entry in column 1 of that Table for that force or service, and
      - (b) a doctor who is not employed or engaged by, and who does not provide services under arrangements made with, any police force or the Police Service of Northern Ireland, and
    - (v) in the case of an arrangement with Her Majesty’s Forces, by or on behalf of a person specified in column 2 of the Table in Part IIA of Schedule 7 to this Order against the entry in column 1 of that Table for Her Majesty’s Forces;]

[ where the prescription only medicine is administered by the person lawfully conducting a <sup>F160</sup>(cc) retail pharmacy business within the meaning of section 69, the individual who administers the medicine belongs to one of the classes of individual specified in Part III of Schedule 7 to this Order, and is [<sup>F161</sup>designated in writing—

- (i) in the case of an arrangement with a body referred to in article 12A(a) to (d), on behalf of that body,
- (ii) in the case of an arrangement with an authority or person carrying on the business of an establishment or agency referred to in article 12D(1), by or on behalf of the relevant provider or, if there is a relevant manager for the establishment or agency, that relevant manager,
- (iii) in the case of an arrangement with a force or service referred to in article 12E(1)(a) (i) to (iii), by or on behalf of the person specified in column 2 of the Table in Part IIA of Schedule 7 to this Order against the entry in column 1 of that Table for that force or service, or
- (iv) in the case of an arrangement with Her Majesty's Forces, by or on behalf of a person specified in column 2 of the Table in Part IIA of Schedule 7 to this Order against the entry in column 1 of that Table for Her Majesty's Forces,

for the purpose of the administration of prescription only medicines under the Patient Group Direction; and]]

- (d) at the time at which the medicine is [<sup>F162</sup>sold or] supplied or, as the case may be, is administered, a product licence, a marketing authorization or a homoeopathic certificate of registration has effect in respect of it.]

#### Textual Amendments

- F143** Arts. 12A-12C inserted (9.8.2000) by The Prescription Only Medicines (Human Use) Amendment Order 2000 (S.I. 2000/1917), arts. 1(1), **2(d)**
- F153** Words in art. 12C(1) inserted (1.9.2007) by The Medicines for Human Use (Administration and Sale or Supply) (Miscellaneous Amendments) Order 2007 (S.I. 2007/2178), arts. 1(1), **3(a)(i)**
- F154** Art. 12C(1)(a) substituted (1.9.2007) by The Medicines for Human Use (Administration and Sale or Supply) (Miscellaneous Amendments) Order 2007 (S.I. 2007/2178), arts. 1(1), **3(a)(ii)**
- F155** Words in art. 12C(1)(b) inserted (1.9.2007) by The Medicines for Human Use (Administration and Sale or Supply) (Miscellaneous Amendments) Order 2007 (S.I. 2007/2178), arts. 1(1), **3(a)(iii)**
- F156** Words in art. 12C(2)(a) inserted (1.9.2007) by The Medicines for Human Use (Administration and Sale or Supply) (Miscellaneous Amendments) Order 2007 (S.I. 2007/2178), arts. 1(1), **3(b)(i)(aa)**
- F157** Words in art. 12C(2)(a) inserted (1.9.2007) by The Medicines for Human Use (Administration and Sale or Supply) (Miscellaneous Amendments) Order 2007 (S.I. 2007/2178), arts. 1(1), **3(b)(i)(bb)**
- F158** Words in art. 12C(2)(a) inserted (1.9.2007) by The Medicines for Human Use (Administration and Sale or Supply) (Miscellaneous Amendments) Order 2007 (S.I. 2007/2178), arts. 1(1), **3(b)(i)(cc)**
- F159** Art. 12C(2)(c) substituted (4.4.2003) by The Prescription Only Medicines (Human Use) Amendment Order 2003 (S.I. 2003/696), arts. 1(1), **10(b)(i)**
- F160** Art. 12C(2)(cc) inserted (16.11.2000) by The Prescription Only Medicines (Human Use) Amendment (No. 2) Order 2000 (S.I. 2000/2899), arts. 1(1), **3(1)**
- F161** Words in art. 12C(2)(cc) substituted (4.4.2003) by The Prescription Only Medicines (Human Use) Amendment Order 2003 (S.I. 2003/696), arts. 1(1), **10(b)(ii)**
- F162** Words in art. 12C(2)(d) inserted (1.9.2007) by The Medicines for Human Use (Administration and Sale or Supply) (Miscellaneous Amendments) Order 2007 (S.I. 2007/2178), arts. 1(1), **3(b)(ii)**

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### **[<sup>F163</sup>Exemption for the supply and administration of prescription only medicines by independent hospitals, clinics and agencies**

**12D.—(1)** The restrictions imposed by section 58(2) (restrictions on sale, supply and administration) shall not apply to the [<sup>F164</sup>sale or] supply or, as the case may be, the administration of a prescription only medicine in the course of the business of—

- [<sup>F165</sup>(a) an independent hospital,
- (b) [<sup>F166</sup>in Wales, Scotland or Northern Ireland,] an independent clinic,
- (c) an independent medical agency, or
- (d) in Northern Ireland, a nursing home,]

where the medicine is [<sup>F167</sup>sold or] supplied for the purpose of being administered, or, as the case may be, is administered, to a particular person in accordance with a Patient Group Direction and where the conditions specified in paragraph (2) are satisfied.

(2) The conditions referred to are that—

- (a) the Patient Group Direction relates to the [<sup>F168</sup>sale or] supply or, as the case may be, the administration, by the person who [<sup>F169</sup>sells or] supplies or administers the medicine, of a description or class of prescription only medicine, and the Direction has effect at the time at which the medicine is [<sup>F170</sup>sold or] supplied or, as the case may be, is administered;
- (b) the Patient Group Direction contains the particulars specified in Part I of Schedule 7 to this Order (but with the omission of paragraph (c) of that Part in the case of a Direction which relates to administration only);
- (c) the Patient Group Direction is signed—
  - (i) by or on behalf of the registered provider, and
  - (ii) if there is a relevant manager for the independent hospital, clinic or agency, or nursing home, by that manager;
- (d) the individual who [<sup>F171</sup>sells or] supplies or, as the case may be, administers the medicine belongs to one of the classes of individual specified in Part III of Schedule 7 to this Order, and is designated in writing—
  - (i) by or on behalf of the registered provider, or
  - (ii) if there is a relevant manager for the independent hospital, clinic or agency, or nursing home, by that manager,

for the purpose of the [<sup>F172</sup>sale or] supply or, as the case may be, the administration of prescription only medicines under the Patient Group Direction; and

- (e) at the time at which the medicine is [<sup>F173</sup>sold or] supplied or, as the case may be, is administered, a product licence, a marketing authorization or a homoeopathic certificate of registration has effect in respect of it.

#### **Textual Amendments**

**F163** Arts. 12D, 12E inserted (4.4.2003) by [The Prescription Only Medicines \(Human Use\) Amendment Order 2003 \(S.I. 2003/696\)](#), arts. 1(1), **11**

**F164** Words in art. 12D(1) inserted (1.9.2007) by [The Medicines for Human Use \(Administration and Sale or Supply\) \(Miscellaneous Amendments\) Order 2007 \(S.I. 2007/2178\)](#), arts. 1(1), **4(a)(i)**

**F165** Art. 12D(1)(a)-(d) substituted for art. 12D(1)(a)(b) (1.9.2007) by [The Medicines for Human Use \(Administration and Sale or Supply\) \(Miscellaneous Amendments\) Order 2007 \(S.I. 2007/2178\)](#), arts. 1(1), **4(a)(ii)**



- F166** Words in art. 12D(1)(b) inserted (1.10.2010) by The Health and Social Care Act 2008 (Miscellaneous Consequential Amendments) Order 2010 (S.I. 2010/1881), arts. 1(1), **9(3)**
- F167** Words in art. 12D(1) inserted (1.9.2007) by The Medicines for Human Use (Administration and Sale or Supply) (Miscellaneous Amendments) Order 2007 (S.I. 2007/2178), arts. 1(1), **4(a)(iii)**
- F168** Words in art. 12D(2)(a) inserted (1.9.2007) by The Medicines for Human Use (Administration and Sale or Supply) (Miscellaneous Amendments) Order 2007 (S.I. 2007/2178), arts. 1(1), **4(b)(i)(aa)**
- F169** Words in art. 12D(2)(a) inserted (1.9.2007) by The Medicines for Human Use (Administration and Sale or Supply) (Miscellaneous Amendments) Order 2007 (S.I. 2007/2178), arts. 1(1), **4(b)(i)(bb)**
- F170** Words in art. 12D(2)(a) inserted (1.9.2007) by The Medicines for Human Use (Administration and Sale or Supply) (Miscellaneous Amendments) Order 2007 (S.I. 2007/2178), arts. 1(1), **4(b)(i)(cc)**
- F171** Words in art. 12D(2)(d) inserted (1.9.2007) by The Medicines for Human Use (Administration and Sale or Supply) (Miscellaneous Amendments) Order 2007 (S.I. 2007/2178), arts. 1(1), **4(b)(ii)(aa)**
- F172** Words in art. 12D(2)(d) inserted (1.9.2007) by The Medicines for Human Use (Administration and Sale or Supply) (Miscellaneous Amendments) Order 2007 (S.I. 2007/2178), arts. 1(1), **4(b)(ii)(bb)**
- F173** Words in art. 12D(2)(e) inserted (1.9.2007) by The Medicines for Human Use (Administration and Sale or Supply) (Miscellaneous Amendments) Order 2007 (S.I. 2007/2178), arts. 1(1), **4(b)(iii)**

**Exemption for health professionals who supply or administer prescription only medicines under a Patient Group Direction in order to assist the provision of health care by or on behalf of the police, the prison services or the armed forces**

**12E.**—(1) The restrictions imposed by section 58(2) (sale, supply and administration) shall not apply to the supply or, as the case may be, the administration of a prescription only medicine by an individual belonging to one of the classes specified in Part III of Schedule 7 to this Order where—

- (a) the individual supplies or, as the case may be, administers the medicine in order to assist the provision of health care by, on behalf of, or under arrangements made by—
- (i) a police force in England, Wales or Scotland,
  - (ii) the Police Service of Northern Ireland,
  - (iii) a prison service, or
  - (iv) Her Majesty's Forces;
- (b) the medicine is supplied for the purpose of being administered, or, as the case may be, is administered, in accordance with a Patient Group Direction; and
- (c) the conditions specified in paragraph (2) are satisfied.
- (2) The conditions referred to are that—
- (a) the Patient Group Direction relates to the supply or, as the case may be, the administration of a description or class of prescription only medicine in order to assist the provision of health care by, or on behalf of, or under arrangements made by the police force or service, the prison service or, as the case may be, Her Majesty's Forces;
  - (b) the Patient Group Direction has effect at the time at which the medicine is supplied or, as the case may be, is administered;
  - (c) the Patient Group Direction contains the particulars specified in Part I of Schedule 7 to this Order (but with the omission of paragraph (c) of that Part in the case of a Direction which relates to administration only);
  - (d) the Patient Group Direction is signed—
    - (i) by or on behalf of a person specified in column 2 of the Table in Part IIA of Schedule 7 to this Order (“the authorising person”) against the entry in column 1 of that Table for the police force or service, the prison service or Her Majesty's

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- Forces by whom, or on whose behalf, the health care is provided, or with whom arrangements are made for the provision of such care; and
- (ii) in the case of a police force or the Police Service of Northern Ireland, by a doctor who is not employed or engaged by, and who does not provide services under arrangements made with, any police force or the Police Service of Northern Ireland;
  - (e) the individual referred to in paragraph (1) is designated in writing, by or on behalf of the authorising person, for the purpose of the supply or, as the case may be, the administration of prescription only medicines under the Patient Group Direction; and
  - (f) at the time at which the medicine is supplied or, as the case may be, is administered, a product licence, a marketing authorization or a homoeopathic certificate of registration has effect in respect of it.]

#### Textual Amendments

**F163** Arts. 12D, 12E inserted (4.4.2003) by [The Prescription Only Medicines \(Human Use\) Amendment Order 2003 \(S.I. 2003/696\)](#), arts. 1(1), **11**

#### [<sup>F174</sup>Exemption for the supply of prescription only medicines in the event or anticipation of pandemic disease

**12F.** The restrictions imposed by section 58(2)(a) (restrictions on sale and supply) shall not apply to the supply of a prescription only medicine by an individual where that supply is—

- (a) made—
  - (i) whilst a disease is, or
  - (ii) in anticipation of a disease being imminently, pandemic and a serious risk, or potentially a serious risk, to human health; and
- (b) in accordance with a protocol which—
  - (i) is approved by—
    - (aa) the Ministers;
    - (bb) an NHS body (within the meaning of article 7A(4)); or
    - (cc) the Health Protection Agency established under section 1 of the Health Protection Agency Act 2004; and
  - (ii) contains criteria as to—
    - (aa) symptoms of, and treatment for, that disease;
    - (bb) the recording of the name of the person who supplies the prescription only medicine to the person to be treated (or to a person acting on that person's behalf) and of the evidence that the medicine was supplied to the person to be treated (or to a person acting on that person's behalf).]

#### Textual Amendments

**F174** Art. 12F inserted (8.5.2009) by [The Medicines for Human Use \(Prescribing\)\(Miscellaneous Amendments\) Order 2009 \(S.I. 2009/1165\)](#), arts. 1, 4

**Exemption in cases involving another's default**

13. The restrictions imposed by section 58(2)(a) (restrictions on sale and supply) shall not apply to the sale or supply of a prescription only medicine by a person who, having exercised all due diligence, believes on reasonable grounds that the product sold or supplied is not a prescription only medicine.

**[<sup>F175</sup>Exemptions relating to prescriptions given by [<sup>F176</sup>certain health professionals]**

13A.—[<sup>F177</sup>(1) The restrictions imposed by section 58(2)(a) (restrictions in sale and supply) shall not apply to the sale or supply of a prescription only medicine by a pharmacist in accordance with a prescription given by—

- (a) another pharmacist,
- (b) a registered nurse, <sup>F178</sup> ...
- (c) a registered midwife, <sup>F179</sup> ...

[<sup>F180</sup>(d) a person whose name is registered in the part of the register maintained by the Health Professions Council in pursuance of article 5 of the Health Professions Order 2001 relating to—

- (i) chiropodists and podiatrists;
- (ii) physiotherapists; or
- (iii) radiographers: diagnostic or therapeutic, [<sup>F181</sup>or]]

[<sup>F182</sup>(e) a registered optometrist,]

who is not an appropriate practitioner in relation to that medicine where the pharmacist selling or supplying the medicine, having exercised all due diligence, believes on reasonable grounds that the person is such a practitioner.]

(2) The restrictions imposed by section 58(2)(a) (restrictions on sale and supply) shall not apply to the sale or supply of a prescription only medicine by a pharmacist in accordance with a prescription given by a <sup>F183</sup>... [<sup>F184</sup> supplementary prescriber] where the pharmacist, having exercised all due diligence, believes on reasonable grounds that [<sup>F185</sup>the <sup>F183</sup>...][<sup>F184</sup> supplementary prescriber] has complied with any condition with which he is required to comply by virtue of [<sup>F186</sup>[<sup>F187</sup>article] 3B].]

**Textual Amendments**

**F175** Art. 13A inserted (1.4.2002) by [The Prescription Only Medicines \(Human Use\) Amendment Order 2002 \(S.I. 2002/549\)](#), arts. 1(1), **7**

**F176** Words in art. 13A heading substituted (1.5.2006) by [The Medicines for Human Use \(Prescribing\) \(Miscellaneous Amendments\) Order 2006 \(S.I. 2006/915\)](#), arts. 1(1), **10(a)**

**F177** Art. 13A(1) substituted (4.4.2003) by [The Prescription Only Medicines \(Human Use\) Amendment Order 2003 \(S.I. 2003/696\)](#), arts. 1(1), **12(a)**

**F178** Word in art. 13A(1)(b) omitted (7.4.2005) by virtue of [The Medicines for Human Use \(Prescribing\) Order 2005 \(S.I. 2005/765\)](#), arts. 1(1), **5(a)**

**F179** Word in art. 13A(1)(c) omitted (30.6.2005) by virtue of [The Medicines for Human Use \(Prescribing\) \(Miscellaneous Amendments\) Order 2005 \(S.I. 2005/1507\)](#), arts. 1(1), **5(a)**

**F180** Art. 13A(1)(d) inserted (7.4.2005) by [The Medicines for Human Use \(Prescribing\) Order 2005 \(S.I. 2005/765\)](#), arts. 1(1), **5(c)**

**F181** Word in art. 13A(d) inserted (30.6.2005) by [The Medicines for Human Use \(Prescribing\) \(Miscellaneous Amendments\) Order 2005 \(S.I. 2005/1507\)](#), arts. 1(1), **5(b)**

**F182** Art. 13A(e) inserted (30.6.2005) by [The Medicines for Human Use \(Prescribing\) \(Miscellaneous Amendments\) Order 2005 \(S.I. 2005/1507\)](#), arts. 1(1), **5(c)**

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*Changes to legislation: There are currently no known outstanding effects for the The Prescription Only Medicines (Human Use) Order 1997. (See end of Document for details)*

- F183** Words in art. 13A(2) omitted (1.4.2008) by virtue of The Prescription Only Medicines (Human Use) Amendment Order 2008 (S.I. 2008/464), arts. 1(1), **9(a)**
- F184** Words in art. 13A(2) inserted (4.4.2003) by The Prescription Only Medicines (Human Use) Amendment Order 2003 (S.I. 2003/696), arts. 1(1), **12(b)(i)**
- F185** Words in art. 13A(2) substituted (1.5.2006) by The Medicines for Human Use (Prescribing) (Miscellaneous Amendments) Order 2006 (S.I. 2006/915), arts. 1(1), **10(b)(ii)**
- F186** Words in art. 13A(2) substituted (4.4.2003) by The Prescription Only Medicines (Human Use) Amendment Order 2003 (S.I. 2003/696), arts. 1(1), **12(b)(ii)**
- F187** Word in art. 13A(2) substituted (1.4.2008) by The Prescription Only Medicines (Human Use) Amendment Order 2008 (S.I. 2008/464), arts. 1(1), **9(b)**

### Exemption in the case of a forged prescription

14. The restrictions imposed by section 58(2)(a) (restrictions on sale and supply) shall not apply to the sale or supply of a prescription only medicine by a pharmacist in accordance with a forged prescription where the pharmacist, having exercised all due diligence, believes on reasonable grounds that the prescription is genuine.

### Prescriptions

<sup>F188</sup>15.—(1) For the purposes of section 58(2)(a), and subject to paragraph (3), a prescription only medicine shall not be taken to be sold or supplied in accordance with a prescription given by an appropriate practitioner unless the conditions specified in paragraph (2) are fulfilled.

- (2) The conditions referred to in paragraph (1) are that the prescription—
- (a) shall be signed in ink with his own name by the appropriate practitioner giving it;
  - (b) shall, without prejudice to sub-paragraph (a), be written in ink or otherwise so as to be indelible, unless it is a health prescription which is not for a controlled drug specified in Schedule 1, 2 or 3 to the Misuse of Drugs Regulations, in which case it may be written by means of carbon paper or similar material;
  - (c) shall contain the following particulars—
    - (i) the address of the appropriate practitioner giving it,
    - (ii) the appropriate date,
    - (iii) such particulars as indicate whether the appropriate practitioner giving it is a doctor, a dentist, a supplementary prescriber, <sup>F189</sup>a community practitioner nurse prescriber, a nurse independent prescriber<sup>F190</sup>, an optometrist independent prescriber], a pharmacist independent prescriber], a veterinary surgeon or a veterinary practitioner,
    - (iv) where the appropriate practitioner giving it is a doctor, dentist, a supplementary prescriber, <sup>F191</sup>a community practitioner nurse prescriber, a nurse independent prescriber<sup>F192</sup>, an optometrist independent prescriber] or a pharmacist independent prescriber] the name, address and the age, if under 12, of the person for whose treatment it is given, and
    - (v) where the appropriate practitioner giving it is a veterinary surgeon or a veterinary practitioner, the name and the address of the person to whom the prescription only medicine is to be delivered and a declaration by the veterinary surgeon or veterinary practitioner giving it that the prescription only medicine is prescribed for an animal or herd under his care;
  - (d) shall not be dispensed after the end of the period of 6 months from the appropriate date, unless it is a repeatable prescription in which case it shall not be dispensed for the first time

after the end of that period nor otherwise than in accordance with the directions contained in the repeatable prescription;

- (e) in the case of a repeatable prescription which does not specify the number of times it may be dispensed, shall not be dispensed on more than two occasions unless it is a prescription for an oral contraceptive in which case it may be dispensed 6 times before the end of the period of 6 months from the appropriate date.

(3) For the purposes of paragraph (1) the prescription may, as an alternative to fulfilling the conditions specified in paragraph (2)(a) and (b), fulfil instead the conditions specified in paragraph (4), unless the prescription is a health prescription for a controlled drug specified in Schedule 1, 2 or 3 to the Misuse of Drugs Regulations or is given by a veterinary surgeon or a veterinary practitioner.

(4) The conditions referred to in paragraph (3) are that the prescription shall be created in electronic form and signed with an advanced electronic signature and transferred to the person by whom it is dispensed as an electronic communication (including where it is so transferred through one or more intermediaries).

(5) The prohibition on sale or supply imposed by section 58(2)(a) shall not apply where a prescription only medicine is sold or supplied other than in accordance with a prescription given by an appropriate practitioner and –

- (a) the reason the sale or supply is not in accordance with such a prescription is that a condition specified in paragraph (2) or (4) is not fulfilled; and
- (b) the person selling or supplying the prescription only medicine has exercised all due diligence and believes on reasonable grounds that the condition is fulfilled.

(6) In paragraph (2) “appropriate date” means—

- (a) in the case of a health prescription, the date on which it was signed by the appropriate practitioner giving it or a date indicated by him as being the date before which it shall not be dispensed; and
- (b) in every other case, the date on which the prescription was signed by the appropriate practitioner giving it,

and, for the purposes of sub-paragraphs (d) and (e) of that paragraph, where the health prescription bears both the date on which it was signed and a date indicated as being that before which it shall not be dispensed, the appropriate date is the later of those dates.

(7) In this Article—

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

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

“electronic communication” means a communication transmitted (whether from one person to another, from one device to another or from a person to a device or vice versa)—

- (a) by means of a telecommunication system (within the meaning of the Telecommunications Act 1984, or
- (b) by other means but while in an electronic form; and

“signatory” means the appropriate practitioner giving the prescription.]

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*Changes to legislation: There are currently no known outstanding effects for the The Prescription Only Medicines (Human Use) Order 1997. (See end of Document for details)*

### Textual Amendments

- F188** Art. 15 substituted (7.4.2005) by [The Medicines for Human Use \(Prescribing\) Order 2005 \(S.I. 2005/765\)](#), arts. 1(1), **6**
- F189** Words in art. 15(2)(c)(iii) substituted (1.5.2006) by [The Medicines for Human Use \(Prescribing\) \(Miscellaneous Amendments\) Order 2006 \(S.I. 2006/915\)](#), arts. 1(1), **11(a)**
- F190** Words in art. 15(2)(c)(iii) inserted (4.6.2008) by [The Medicines for Human Use \(Prescribing\) \(Miscellaneous Amendments\) Order 2008 \(S.I. 2008/1161\)](#), arts. 1(1), **5(a)**
- F191** Words in art. 15(2)(c)(iv) substituted (1.5.2006) by [The Medicines for Human Use \(Prescribing\) \(Miscellaneous Amendments\) Order 2006 \(S.I. 2006/915\)](#), arts. 1(1), **11(b)**
- F192** Words in art. 15(2)(c)(iv) inserted (4.6.2008) by [The Medicines for Human Use \(Prescribing\) \(Miscellaneous Amendments\) Order 2008 \(S.I. 2008/1161\)](#), arts. 1(1), **5(b)**

### Revocations

**16.**—(1) The Orders specified in Schedule 6 are revoked.

(2) In the Medicines (Prescription Only, Pharmacy and General Sale) Amendment Order 1989(**13**) articles 2 to 6 and Schedules 1 and 2 are revoked.

Signed by authority of the Secretary of State for Health

*Baroness Jay*  
Minister of State,  
Department of Health

*Win Griffiths*  
Parliamentary Under Secretary of State, Welsh  
Office

*Sam Galbraith*  
Parliamentary Under Secretary of State, The  
Scottish Office

*Jeff Rooker*  
Minister of State, Ministry of Agriculture,  
Fisheries and Food

Sealed with the Official Seal of the Department of Health and Social Services for Northern Ireland on 22nd July 1997.



*D. C. Gowdy*  
Permanent Secretary

Sealed with the Official Seal of the Department of Agriculture for Northern Ireland on 18th July 1997.



*P. Small*  
Permanent Secretary

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SCHEDULE 1

Articles 3(a), 5(1) and 10

SUBSTANCES WHICH IF INCLUDED IN MEDICINAL PRODUCTS MAKE THOSE PRODUCTS PRESCRIPTION ONLY MEDICINES AND EXEMPTIONS FROM RESTRICTIONS ON THE SALE AND SUPPLY OF PRESCRIPTION ONLY MEDICINES

| <i>Exemptions from the restrictions on the sale and supply of prescription only medicines</i> |                                      |   |   |   |
|---|--------------------------------------|---|---|---|
| <i>Column 1<br/>Substance</i>   | <i>Column 2<br/>Maximum strength</i> | <i>Column 3<br/>Route of administration, use or pharmaceutical form</i>                 | <i>Column 4<br/>Treatment limitations</i> | <i>Column 5<br/>Maximum quantity</i>                                  |
| [ <sup>F193</sup> Acamprosate]  |                                      |   |   |   |
| Acarbose  |                                      |   |   |   |
| Acebutolol Hydrochloride  |                                      |   |   |   |
| [ <sup>F193</sup> Aceclofenac]  |                                      |   |   |   |
| Acemetacin  |                                      |   |   |   |
| Acetarsol   |                                      |   |   |   |
| Acetazolamide   |                                      |   |   |   |
| Acetazolamide Sodium  |                                      |   |   |   |
| Acetohexamide   |                                      |   |   |   |
| Acetylcholine   | 0.2 per cent                         | External Chloride   |   |   |
| Acetylcysteine  |                                      |   |   |   |
| Acipimox  |                                      |   |   |   |
| Aciclovir   | 5.0 per cent                         | External  |   | Container or package containing not more than 2g of medicinal product |
|   |                                      | For treatment of herpes simplex virus infections of the lips and face (Herpes labialis) |   |   |
| Acitretin   |                                      |   |   |   |
| Aclarubicin Hydrochloride   |                                      |   |   |   |
| Aconite   | 1.3 per cent                         | External  |   |   |



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| <i>Exemptions from the restrictions on the sale and supply of prescription only medicines</i> |                                      |   |   |  |
|---|--------------------------------------|---|---|--|
| <i>Column 1<br/>Substance</i>   | <i>Column 2<br/>Maximum strength</i> | <i>Column 3<br/>Route of administration, use or pharmaceutical form</i>   | <i>Column 4<br/>Treatment limitations</i> | <i>Column 5<br/>Maximum quantity</i>                               |
| Acrivastine   |                                      |   | 24 mg (MDD)                               | Container or package containing not more than 240mg of Acrivastine |
| Acrosoxacin   |                                      |   |   |  |
| Actinomycin C   |                                      |   |   |  |
| Actinomycin D   |                                      |   |   |  |
| [ <sup>194</sup> F]Adapalene]   |                                      |   |   |  |
| Adenosine   |                                      |   |   |  |
| Adrenaline  |                                      | (1) By inhaler<br><br>(2) External [ <sup>195</sup> F(except ophthalmic)] |   |  |
| Adrenaline Acid Tartrate  |                                      | (1) By inhaler<br><br>(2) External  |   |  |
| Adrenaline Hydrochloride  |                                      | (1) By inhaler<br><br>(2) External  |   |  |
| Adrenocortical Extract  |                                      |   |   |  |
| Albendazole   |                                      |   |   |  |
| Alclofenac  |                                      |   |   |  |
| Alclometasone Dipropionate  |                                      |   |   |  |
| Alcuronium Chloride   |                                      |   |   |  |
| Aldesleukin   |                                      |   |   |  |
| Aldosterone   |                                      |   |   |  |

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| <i>Exemptions from the restrictions on the sale and supply of prescription only medicines</i> |                                      |   |   |  |
|---|--------------------------------------|---|---|--|
| <i>Column 1<br/>Substance</i>   | <i>Column 2<br/>Maximum strength</i> | <i>Column 3<br/>Route of administration, use or pharmaceutical form</i> | <i>Column 4<br/>Treatment limitations</i> | <i>Column 5<br/>Maximum quantity</i>   |
| [ <sup>F193</sup> Alendronate Sodium]   |                                      |   |   |  |
| Alfacalcidol  |                                      |   |   |  |
| Alfuzosin Hydrochloride   |                                      |   |   |  |
| Allergen Extracts   |                                      |   |   |  |
| Allopurinol   |                                      |   |   |  |
| Allyloestrenol  |                                      |   |   |  |
| [ <sup>F196</sup> Aloxiprin (1) 620 mg  |                                      | (1) Non-effervescent tablets and capsules                               |   | (1) The quantity sold or supplied in one container or package shall not exceed 32<br><br>The quantity of non-effervescent tablets, capsules or a combination of both sold or supplied to a person at any one time shall not exceed 100 |
|   |                                      | (2) All preparations other than non-effervescent tablets or capsules]   |   |  |

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**Changes to legislation:** There are currently no known outstanding effects for the The Prescription Only Medicines (Human Use) Order 1997. (See end of Document for details)

| <i>Exemptions from the restrictions on the sale and supply of prescription only medicines</i> |                                      |   |   |                                      |
|---|--------------------------------------|---|---|--------------------------------------|
| <i>Column 1<br/>Substance</i>   | <i>Column 2<br/>Maximum strength</i> | <i>Column 3<br/>Route of administration, use or pharmaceutical form</i> | <i>Column 4<br/>Treatment limitations</i> | <i>Column 5<br/>Maximum quantity</i> |
| Alphadolone Acetate   |                                      |   |   |                                      |
| Alphaxalone   |                                      |   |   |                                      |
| Alprenolol  |                                      |   |   |                                      |
| Alprenolol Hydrochloride  |                                      |   |   |                                      |
| Alprostadil   |                                      |   |   |                                      |
| Alseroxylon   |                                      |   |   |                                      |
| [ <sup>194</sup> F]Altretamine]   |                                      |   |   |                                      |
| Amantadine Hydrochloride  |                                      |   |   |                                      |
| Amibenonium Chloride  |                                      |   |   |                                      |
| Ambutonium Bromide  |                                      |   |   |                                      |
| Amcinonide  |                                      |   |   |                                      |
| Ametazole Hydrochloride   |                                      |   |   |                                      |
| Amethocaine   |                                      | Non-ophthalmic use  |   |                                      |
| Amethocaine Gentsiate   |                                      | Non-ophthalmic use  |   |                                      |
| Amethocaine Hydrochloride   |                                      | Non-ophthalmic use  |   |                                      |
| Amikacin Sulphate   |                                      |   |   |                                      |
| Amiloride Hydrochloride   |                                      |   |   |                                      |
| Aminocaproic Acid   |                                      |   |   |                                      |
| Aminoglutethimide   |                                      |   |   |                                      |

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| <i>Exemptions from the restrictions on the sale and supply of prescription only medicines</i> |                                      |   |   |                                      |
|---|--------------------------------------|---|---|--------------------------------------|
| <i>Column 1<br/>Substance</i>   | <i>Column 2<br/>Maximum strength</i> | <i>Column 3<br/>Route of administration, use or pharmaceutical form</i> | <i>Column 4<br/>Treatment limitations</i> | <i>Column 5<br/>Maximum quantity</i> |
| Aminopterin Sodium  |                                      |   |   |                                      |
| Amiodarone Hydrochloride  |                                      |   |   |                                      |
| Amiphenazole Hydrochloride  |                                      |   |   |                                      |
| [ <sup>197</sup> F]Amisulpride]   |                                      |   |   |                                      |
| Amitriptyline   |                                      |   |   |                                      |
| Amitriptyline Embonate  |                                      |   |   |                                      |
| Amitriptyline Hydrochloride   |                                      |   |   |                                      |
| Amlodipine Besylate   |                                      |   |   |                                      |
| Ammonium Bromide  |                                      |   |   |                                      |
| Amodiaquine Hydrochloride   |                                      |   |   |                                      |
| Amorolfine Hydrochloride  |                                      |   |   |                                      |
| Amoxapine   |                                      |   |   |                                      |
| Amoxicillin   |                                      |   |   |                                      |
| Amoxicillin Sodium  |                                      |   |   |                                      |
| Amoxicillin Trihydrate  |                                      |   |   |                                      |
| Amphomycin Calcium  |                                      |   |   |                                      |
| Amphotericin  |                                      |   |   |                                      |
| Ampicillin  |                                      |   |   |                                      |
| Ampicillin Sodium   |                                      |   |   |                                      |
| Ampicillin Trihydrate   |                                      |   |   |                                      |

| <i>Exemptions from the restrictions on the sale and supply of prescription only medicines</i> |                                      |   |   |                                      |
|---|--------------------------------------|---|---|--------------------------------------|
| <i>Column 1<br/>Substance</i>   | <i>Column 2<br/>Maximum strength</i> | <i>Column 3<br/>Route of administration, use or pharmaceutical form</i> | <i>Column 4<br/>Treatment limitations</i> | <i>Column 5<br/>Maximum quantity</i> |
| Amsacrine   |                                      |   |   |                                      |
| Amygdalin   |                                      |   |   |                                      |
| Amyl Nitrite  |                                      |   |   |                                      |
| Amylocaine Hydrochloride  |                                      | Non-ophthalmic use  |   |                                      |
| [ <sup>193</sup> F]Anastrozole]   |                                      |   |   |                                      |
| Ancrod  |                                      |   |   |                                      |
| Androsterone  |                                      |   |   |                                      |
| Angiotensin Amide   |                                      |   |   |                                      |
| Anistreplase  |                                      |   |   |                                      |
| Anterior Pituitary Extract  |                                      |   |   |                                      |
| Antimony Barium Tartrate  |                                      |   |   |                                      |
| Antimony Dimercaptosuccinate  |                                      |   |   |                                      |
| Antimony Lithium Thiomalate   |                                      |   |   |                                      |
| Antimony Pentasulphide  |                                      |   |   |                                      |
| Antimony Potassium Tartrate   |                                      |   |   |                                      |
| Antimony Sodium Tartrate  |                                      |   |   |                                      |
| Antimony Sodium Thioglycollate  |                                      |   |   |                                      |

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| <i>Exemptions from the restrictions on the sale and supply of prescription only medicines</i> |  |   |   |  |
|---|--|---|---|--|
| <i>Column 1<br/>Substance</i>   | <i>Column 2<br/>Maximum<br/>strength</i> | <i>Column 3<br/>Route of<br/>administration,<br/>use or<br/>pharmaceutical<br/>form</i> | <i>Column 4<br/>Treatment limitations</i> | <i>Column 5<br/>Maximum<br/>quantity</i> |
| Antimony Sulphate   |  |   |   |  |
| Antimony Trichloride  |  |   |   |  |
| Antimony Trioxide   |  |   |   |  |
| Antimony Trisulphide  |  |   |   |  |
| Apiol   |  |   |   |  |
| Apomorphine   |  |   |   |  |
| Apomorphine Hydrochloride   |  |   |   |  |
| [ <sup>194</sup> F]Apraclonidine Hydrochloride]   |  |   |   |  |
| Aprotinin   |  |   |   |  |
| Arecoline Hydrobromide  |  |   |   |  |
| Argipressin   |  |   |   |  |
| Aristolochia  |  |   |   |  |
| Aristolochia Clematidis   |  |   |   |  |
| Aristolochia Contorta   |  |   |   |  |
| Aristolochia Debelis  |  |   |   |  |
| Aristolochia Fang-chi   |  |   |   |  |
| Aristolochia Manshuriensis  |  |   |   |  |
| Aristolochia Serpentaria  |  |   |   |  |
| Arsenic   |  |   |   |  |
| Arsenic Triiodide   |  |   |   |  |

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| <i>Exemptions from the restrictions on the sale and supply of prescription only medicines</i> |   |   |   |  |
|---|---|---|---|--|
| <i>Column 1<br/>Substance</i>   | <i>Column 2<br/>Maximum strength</i>            | <i>Column 3<br/>Route of administration, use or pharmaceutical form</i> | <i>Column 4<br/>Treatment limitations</i> | <i>Column 5<br/>Maximum quantity</i>   |
| Arsenic Trioxide  |   |   |   |  |
| Arsphenamine  |   |   |   |  |
| [ <sup>F198</sup> Aspirin   | [ <sup>F199</sup> (1) 75mg]                     | [ <sup>F199</sup> (1) Non-effervescent tablets and capsules]            |   | [ <sup>F199</sup> (1) The quantity sold or supplied in one container or package shall not exceed 100<br>The quantity of non-effervescent tablets, capsules or a combination of both sold or supplied to a person at any one time shall not exceed 100] |
|   | [ <sup>F200</sup> [ <sup>F200</sup> (2)] 300mg] | [ <sup>F201</sup> (2) Non-effervescent tablets and capsules]            |   | [ <sup>F201</sup> (2)] The quantity sold or supplied in one container or package   |

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| <i>Exemptions from the restrictions on the sale and supply of prescription only medicines</i> |                                      |   |   |  |
|---|--------------------------------------|---|---|--|
| <i>Column 1<br/>Substance</i>   | <i>Column 2<br/>Maximum strength</i> | <i>Column 3<br/>Route of administration, use or pharmaceutical form</i>                 | <i>Column 4<br/>Treatment limitations</i> | <i>Column 5<br/>Maximum quantity</i>   |
|   |                                      |   |   | shall not exceed 32  |
|   |                                      | [ <sup>F201</sup> (3)] All preparations other than non-effervescent tablets or capsules |   | The quantity of non-effervescent tablets, capsules or a combination of both sold or supplied to a person at any one time shall not exceed 100] |
| Astemizole  | F202                                 |   | F202                                      | F202   |
|   | ...                                  |   | ...                                       | ...  |
|   | F202                                 |   |   |  |
|   | ...                                  |   |   |  |
|   | F202                                 |   |   |  |
|   | ...                                  |   |   |  |
| Atenolol  |                                      |   |   |  |
| Atracurium Besylate   |                                      |   |   |  |
| Atropine  |                                      | (1) Internal<br>(a) by inhaler<br>(b) otherwise   | (b) 300mcg (MD)                           |  |



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| <i>Exemptions from the restrictions on the sale and supply of prescription only medicines</i> |                                      |   |   |                                      |
|---|--------------------------------------|---|---|--------------------------------------|
| <i>Column 1<br/>Substance</i>   | <i>Column 2<br/>Maximum strength</i> | <i>Column 3<br/>Route of administration, use or pharmaceutical form</i> | <i>Column 4<br/>Treatment limitations</i> | <i>Column 5<br/>Maximum quantity</i> |
|   |                                      | than by inhaler   |   |                                      |
|   |                                      |   | 1mg (MDD)                                 |                                      |
|   |                                      | (2) External (except ophthalmic)  |   |                                      |
| Atropine Methobromide   |                                      | (1) Internal (a) by inhaler   |   |                                      |
|   |                                      | (b) otherwise than by inhaler   | (b) 400mcg (MD)                           |                                      |
|   |                                      |   | 1.3mg (MDD)                               |                                      |
|   |                                      | (2) External (except ophthalmic)  |   |                                      |
| Atropine Methonitrate   |                                      | Internal (a) by inhaler   |   |                                      |
|   |                                      | (b) otherwise than by inhaler   | (b) 400mcg (MD)                           |                                      |
|   |                                      |   | 1.3mg (MDD)                               |                                      |
| Atropine Oxide Hydrochloride  |                                      | (1) Internal (a) by inhaler   |   |                                      |
|   |                                      | (b) otherwise than by inhaler   | (b) 360mcg (MD)                           |                                      |
|   |                                      |   | 1.2mg (MDD) 3                             |                                      |
|   |                                      | (2) External (except ophthalmic)  |   |                                      |

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| <i>Exemptions from the restrictions on the sale and supply of prescription only medicines</i> |                                      |   |   |  |
|---|--------------------------------------|---|---|--|
| <i>Column 1<br/>Substance</i>   | <i>Column 2<br/>Maximum strength</i> | <i>Column 3<br/>Route of administration, use or pharmaceutical form</i>   | <i>Column 4<br/>Treatment limitations</i>               | <i>Column 5<br/>Maximum quantity</i>   |
| Atropine Sulphate   |                                      | (1) Internal<br>(a) by inhaler<br>(b) otherwise than by inhaler   | (b) 360mcg (MD)<br><br>1.2mg (MDD)                      |  |
| Auranofin   |                                      |   |   |  |
| Azapropazone  |                                      |   |   |  |
| Azathioprine  |                                      |   |   |  |
| Azathioprine Sodium   |                                      |   |   |  |
| Azelaic Acid  |                                      |   |   |  |
| Azelastine Hydrochloride  |                                      | For nasal administration<br><br>For the treatment of seasonal allergic rhinitis [F203 or perennial allergic rhinitis]<br><br>For use in adults and children not less than [F204 5 years]<br><br>As a non-aerosol, | 140mcg per nostril (MD)<br><br>280mcg per nostril (MDD) | Container or package containing not more than 5,040mcg of Azelastine Hydrochloride |

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| <i>Exemptions from the restrictions on the sale and supply of prescription only medicines</i> |                                      |   |   |   |
|---|--------------------------------------|---|---|---|
| <i>Column 1<br/>Substance</i>   | <i>Column 2<br/>Maximum strength</i> | <i>Column 3<br/>Route of administration, use or pharmaceutical form</i> | <i>Column 4<br/>Treatment limitations</i> | <i>Column 5<br/>Maximum quantity</i>  |
|   |                                      | aqueous form  |   |   |
| Azidocillin Potassium   |                                      |   |   |   |
| Azithromycin  |                                      |   |   |   |
| Azlocillin Sodium   |                                      |   |   |   |
| Aztreonam   |                                      |   |   |   |
| Bacampicillin Hydrochloride   |                                      |   |   |   |
| Bacitracin  |                                      |   |   |   |
| Bacitracin Methylene Disalicylate   |                                      |   |   |   |
| Bacitracin Zinc   |                                      |   |   |   |
| Baclofen  |                                      |   |   |   |
| [ <sup>197</sup> F]Balsalazide Sodium]  |                                      |   |   |   |
| Bambuterol Hydrochloride  |                                      |   |   |   |
| Barium Carbonate  |                                      |   |   |   |
| Barium Chloride   |                                      |   |   |   |
| Barium Sulphide   |                                      |   |   |   |
| Beclamide   |                                      |   |   |   |
| Beclomethasone Dipropionate   |                                      | For nasal administration (non-aerosol)                                  | 100mcg per nostril (MD)                   | Container or package containing not more than [ <sup>205</sup> F]20,000 mcg] of |

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| <i>Exemptions from the restrictions on the sale and supply of prescription only medicines</i> |  |   |  |  |
|---|--|---|--|--|
| <i>Column 1<br/>Substance</i>   | <i>Column 2<br/>Maximum<br/>strength</i> | <i>Column 3<br/>Route of<br/>administration,<br/>use or<br/>pharmaceutical<br/>form</i> | <i>Column 4<br/>Treatment limitations</i>  | <i>Column 5<br/>Maximum<br/>quantity</i> |
|   |  | For the prevention and treatment of allergic rhinitis                                   | 200 mcg per nostril (MDD)<br>[ <sup>F206</sup> For a maximum period of 3 months] | Beclomethasone Dipropionate              |
|   |  | [ <sup>F207</sup> For use in persons aged 18 years and over]                            |  |  |
| Belladonna Herb   |  | (1) Internal<br>(2) External  | (1) 1mg of the alkaloids (MDD)   |  |
| Belladonna Root   |  | (1) Internal<br>(2) External  | (1) 1mg of the alkaloids (MDD)   |  |
| Bemegride   |  |   |  |  |
| Bemegride Sodium  |  |   |  |  |
| Benapryzine Hydrochloride   |  |   |  |  |
| Bendrofluazide  |  |   |  |  |
| Benethamine Penicillin  |  |   |  |  |
| Benoxaprofen  |  |   |  |  |
| Benperidol  |  |   |  |  |
| [ <sup>F197</sup> Benserazide]  |  |   |  |  |
| Benserazide Hydrochloride   |  |   |  |  |
| Bentiromide   |  |   |  |  |
| Benzathine Penicillin   |  |   |  |  |
| Benzbromarone   |  |   |  |  |

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| <i>Exemptions from the restrictions on the sale and supply of prescription only medicines</i> |                                      |   |   |                                      |
|---|--------------------------------------|---|---|--------------------------------------|
| <i>Column 1<br/>Substance</i>   | <i>Column 2<br/>Maximum strength</i> | <i>Column 3<br/>Route of administration, use or pharmaceutical form</i> | <i>Column 4<br/>Treatment limitations</i> | <i>Column 5<br/>Maximum quantity</i> |
| Benzhexol Hydrochloride   |                                      |   |   |                                      |
| Benzilonium Bromide   |                                      |   |   |                                      |
| Benzocaine  |                                      | Any use except ophthalmic use   |   |                                      |
| Benzocetamine Hydrochloride   |                                      |   |   |                                      |
| Benzoyl Peroxide  | 10.0 per cent                        | External  |   |                                      |
| N-Benzoyl Sulphanilamide  |                                      |   |   |                                      |
| Benzquinamide   |                                      |   |   |                                      |
| Benzquinamide Hydrochloride   |                                      |   |   |                                      |
| Benzthiazide  |                                      |   |   |                                      |
| Benztropine Mesylate  |                                      |   |   |                                      |
| Benzylpenicillin Calcium  |                                      |   |   |                                      |
| Benzylpenicillin Potassium  |                                      |   |   |                                      |
| Benzylpenicillin Sodium   |                                      |   |   |                                      |
| Beractant   |                                      |   |   |                                      |
| Betahistine Hydrochloride   |                                      |   |   |                                      |
| Betamethasone   |                                      |   |   |                                      |
| Betamethasone Adamantoate   |                                      |   |   |                                      |
| Betamethasone Benzoate  |                                      |   |   |                                      |

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| <i>Exemptions from the restrictions on the sale and supply of prescription only medicines</i> |  |   |   |  |
|---|--|---|---|--|
| <i>Column 1<br/>Substance</i>   | <i>Column 2<br/>Maximum<br/>strength</i> | <i>Column 3<br/>Route of<br/>administration,<br/>use or<br/>pharmaceutical<br/>form</i> | <i>Column 4<br/>Treatment limitations</i> | <i>Column 5<br/>Maximum<br/>quantity</i> |
| Betamethasone<br>Dipropionate   |  |   |   |  |
| Betamethasone<br>Sodium<br>Phosphate  |  |   |   |  |
| Betamethasone<br>Valerate   |  |   |   |  |
| Betaxolol<br>Hydrochloride  |  |   |   |  |
| Bethanechol<br>Chloride   |  |   |   |  |
| Bethanidine<br>Sulphate   |  |   |   |  |
| Bezafibrate   |  |   |   |  |
| [ <sup>194</sup> F]Bicalutamide]  |  |   |   |  |
| Biperiden<br>Hydrochloride  |  |   |   |  |
| Biperiden<br>Lactate  |  |   |   |  |
| Bismuth<br>Glycollylarsanilate  |  |   |   |  |
| Bisoprolol<br>Fumarate  |  |   |   |  |
| Bleomycin   |  |   |   |  |
| Bleomycin<br>Sulphate   |  |   |   |  |
| Bretylium<br>Tosylate   |  |   |   |  |
| [ <sup>197</sup> F]Brimonidine<br>Tartrate]   |  |   |   |  |
| Bromhexine<br>Hydrochloride   |  |   |   |  |
| Bromocriptine<br>Mesylate   |  |   |   |  |
| Bromperidol   |  |   |   |  |

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| <i>Exemptions from the restrictions on the sale and supply of prescription only medicines</i> |                                      |  |  |  |
|---|--------------------------------------|--|--|--|
| <i>Column 1<br/>Substance</i>   | <i>Column 2<br/>Maximum strength</i> | <i>Column 3<br/>Route of administration, use or pharmaceutical form</i>  | <i>Column 4<br/>Treatment limitations</i>  | <i>Column 5<br/>Maximum quantity</i>                             |
| Bromvaletone  |                                      |  |  |  |
| Brotizolam  |                                      |  |  |  |
| Budesonide  |                                      | For nasal administration<br><br>For the prevention or treatment of seasonal allergic rhinitis<br><br>200 mcg per nostril (MDD)<br><br>[ <sup>F207</sup> For use in persons aged 18 years and over]<br><br>As a non-aerosol, aqueous form | 200mcg per nostril (MD)<br><br>[ <sup>F206</sup> For a maximum period of 3 months] | Container or package containing not more than 10mg of Budesonide |
| Bufexamac   |                                      |  |  |  |
| Bumetanide  |                                      |  |  |  |
| Buphenine Hydrochloride   |                                      |  | 6mg (MD)<br>18mg (MDD)   |  |
| Bupivacaine   |                                      | Any use except ophthalmic use  |  |  |
| Bupivacaine Hydrochloride   |                                      | Any use except ophthalmic use  |  |  |
| Buserelin Acetate   |                                      |  |  |  |

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| <i>Exemptions from the restrictions on the sale and supply of prescription only medicines</i> |  |   |   |  |
|---|--|---|---|--|
| <i>Column 1<br/>Substance</i>   | <i>Column 2<br/>Maximum<br/>strength</i> | <i>Column 3<br/>Route of<br/>administration,<br/>use or<br/>pharmaceutical<br/>form</i> | <i>Column 4<br/>Treatment limitations</i> | <i>Column 5<br/>Maximum<br/>quantity</i> |
| Buspirone<br>Hydrochloride  |  |   |   |  |
| Busulphan   |  |   |   |  |
| Butacaine<br>Sulphate   |  | Any use<br>except<br>ophthalmic<br>use  |   |  |
| Butorphanol<br>Tartrate   |  |   |   |  |
| Butriptyline<br>Hydrochloride   |  |   |   |  |
| [ <sup>F208</sup> Cabergoline]  |  |   |   |  |
| Calcipotriol  |  |   |   |  |
| [ <sup>F194</sup> Calcipotriol<br>Hydrate]  |  |   |   |  |
| Calcitonin  |  |   |   |  |
| Calcitriol  |  |   |   |  |
| Calcium<br>Amphomycin   |  |   |   |  |
| Calcium<br>Benzamidosalicylate  |  |   |   |  |
| Calcium<br>Bromide  |  |   |   |  |
| Calcium<br>Bromidolactobionate  |  |   |   |  |
| Calcium<br>Carbimide  |  |   |   |  |
| Calcium<br>Folinate   |  |   |   |  |
| Calcium<br>Metrizoate   |  |   |   |  |
| Calcium<br>Sulphaloxate   |  |   |   |  |
| [ <sup>F209</sup> Candesartan<br>Cilexetil]   |  |   |   |  |



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|---|--|---|---|---|
| <i>Column 1<br/>Substance</i>   | <i>Column 2<br/>Maximum<br/>strength</i> | <i>Column 3<br/>Route of<br/>administration,<br/>use or<br/>pharmaceutical<br/>form</i> | <i>Column 4<br/>Treatment limitations</i> | <i>Column 5<br/>Maximum<br/>quantity</i>  |
| Candicidin  |  |   |   |   |
| Canrenoic Acid  |  |   |   |   |
| Cantharidin   | 0.01 per cent                            | External  |   |   |
| Capreomycin Sulphate  |  |   |   |   |
| Captopril   |  |   |   |   |
| Carbachol   |  |   |   |   |
| Carbamazepine   |  |   |   |   |
| Carbaryl  |  |   |   |   |
| [ <sup>197</sup> F]Carbasalate Calcium]   |  |   |   |   |
| Carbenicillin Sodium  |  |   |   |   |
| Carbenoxolone Sodium  |  | (1) Pellet  | (1) 5mg (MD)<br>25mg (MDD)                |   |
|   | (2) 2.0 per cent                         | (2) Gel   |   |   |
|   | (3) 1.0 per cent                         | (3) Granules for mouthwash in adults and children not less than 12 years                | (3) 20mg (MD)<br>80mg (MDD)               | (3) Container or package containing not more than [ <sup>210</sup> F]560mg] of Carbenoxolone Sodium |
| Carbidopa   |  |   |   |   |
| Carbimazole   |  |   |   |   |
| Carbocisteine   |  |   |   |   |
| Carbon Tetrachloride  |  |   |   |   |
| Carboplatin   |  |   |   |   |

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|---|--|---|---|--|
| <i>Column 1<br/>Substance</i>   | <i>Column 2<br/>Maximum<br/>strength</i> | <i>Column 3<br/>Route of<br/>administration,<br/>use or<br/>pharmaceutical<br/>form</i> | <i>Column 4<br/>Treatment limitations</i> | <i>Column 5<br/>Maximum<br/>quantity</i> |
| Carboprost  |  |   |   |  |
| Trometamol  |  |   |   |  |
| Carbuterol<br>Hydrochloride   |  |   |   |  |
| Carfecillin<br>Sodium   |  |   |   |  |
| Carindacillin<br>Sodium   |  |   |   |  |
| Carisoprodol  |  |   |   |  |
| Carmustine  |  |   |   |  |
| Carperidine   |  |   |   |  |
| Carteolol<br>Hydrochloride  |  |   |   |  |
| Cefaclor  |  |   |   |  |
| Cefadroxil  |  |   |   |  |
| Cefazedone<br>Sodium  |  |   |   |  |
| [ <sup>F197</sup> Cefdinir]   |  |   |   |  |
| Cefixime  |  |   |   |  |
| Cefodizime<br>Sodium  |  |   |   |  |
| Cefotaxime<br>Sodium  |  |   |   |  |
| Cefoxitin<br>Sodium   |  |   |   |  |
| Cefpodoxime<br>Proxetil   |  |   |   |  |
| [ <sup>F208</sup> Cefprozil]  |  |   |   |  |
| Cefsulodin<br>Sodium  |  |   |   |  |
| Ceftazidime   |  |   |   |  |
| Ceftizoxime<br>Sodium   |  |   |   |  |

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| <i>Exemptions from the restrictions on the sale and supply of prescription only medicines</i> |                                      |   |   |                                      |
|---|--------------------------------------|---|---|--------------------------------------|
| <i>Column 1<br/>Substance</i>   | <i>Column 2<br/>Maximum strength</i> | <i>Column 3<br/>Route of administration,<br/>use or pharmaceutical form</i> | <i>Column 4<br/>Treatment limitations</i> | <i>Column 5<br/>Maximum quantity</i> |
| Ceftriaxone Sodium  |                                      |   |   |                                      |
| Cefuroxime Axetil   |                                      |   |   |                                      |
| Cefuroxime Sodium   |                                      |   |   |                                      |
| Celiprolol Hydrochloride  |                                      |   |   |                                      |
| Cephalexin  |                                      |   |   |                                      |
| Cephalexin Sodium   |                                      |   |   |                                      |
| Cephaloridine   |                                      |   |   |                                      |
| Cephalothin Sodium  |                                      |   |   |                                      |
| Cephmandole Nafate  |                                      |   |   |                                      |
| Cephazolin Sodium   |                                      |   |   |                                      |
| Cephradine  |                                      |   |   |                                      |
| Cerium Oxalate  |                                      |   |   |                                      |
| Cerivastatin  |                                      |   |   |                                      |
| [ <sup>197</sup> F]Cerivastatin Sodium]   |                                      |   |   |                                      |
| Ceruletide Diethylamine   |                                      |   |   |                                      |
| Cetirizine Hydrochloride  |                                      |   | 10mg (MDD)                                | F211<br>...                          |
| Chenodeoxycholic Acid   |                                      |   |   |                                      |
| Chloral Hydrate   |                                      | External  |   |                                      |
| Chlorambucil  |                                      |   |   |                                      |
| Chloramphenicol   |                                      |   |   |                                      |

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|---|--|---|---|--|
| <i>Column 1<br/>Substance</i>   | <i>Column 2<br/>Maximum<br/>strength</i> | <i>Column 3<br/>Route of<br/>administration,<br/>use or<br/>pharmaceutical<br/>form</i> | <i>Column 4<br/>Treatment limitations</i> | <i>Column 5<br/>Maximum<br/>quantity</i> |
| Chloramphenicol<br>Cinnamate  |  |   |   |  |
| Chloramphenicol<br>Palmitate  |  |   |   |  |
| Chloramphenicol<br>Sodium<br>Succinate  |  |   |   |  |
| Chlorhexadol  |  |   |   |  |
| Chlormadinone<br>Acetate  |  |   |   |  |
| Chlormerodrin   |  |   |   |  |
| Chlormethiazole   |  |   |   |  |
| Chlormethiazole<br>Edisylate  |  |   |   |  |
| Chlormezanone   |  |   |   |  |
| Chloroform(14) 5.0 per<br>cent  |  | (1) Internal<br><br>(2) External  |   |  |
| Chloroquine<br>Phosphate  |  | Prophylaxis<br>of malaria   |   |  |
| Chloroquine<br>Sulphate   |  | Prophylaxis<br>of malaria   |   |  |
| Chlorothiazide  |  |   |   |  |
| Chlorotrianisene  |  |   |   |  |
| Chlorphenoxamine<br>Hydrochloride   |  |   |   |  |
| Chlorpromazine  |  |   |   |  |
| Chlorpromazine<br>Embonate  |  |   |   |  |
| Chlorpromazine<br>Hydrochloride   |  |   |   |  |
| Chlorpropamide  |  |   |   |  |

(14) See S.I. 1979/382 amended by S.I. 1980/263 and S.I. 1989/1124.

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|---|--------------------------------------|---|---|--------------------------------------|
| <i>Column 1<br/>Substance</i>   | <i>Column 2<br/>Maximum strength</i> | <i>Column 3<br/>Route of administration, use or pharmaceutical form</i>   | <i>Column 4<br/>Treatment limitations</i>   | <i>Column 5<br/>Maximum quantity</i> |
| Chlorprothixene   |                                      |   |   |                                      |
| Chlorprothixene Hydrochloride   |                                      |   |   |                                      |
| Chlortetracycline   |                                      |   |   |                                      |
| Chlortetracycline Calcium   |                                      |   |   |                                      |
| Chlortetracycline Hydrochloride   |                                      |   |   |                                      |
| Chlorthalidone  |                                      |   |   |                                      |
| Chlorzoxazone   |                                      |   |   |                                      |
| Cholestyramine  |                                      |   |   |                                      |
| Ciclacillin   |                                      |   |   |                                      |
| Ciclobendazole  |                                      |   |   |                                      |
| Cilastatin Sodium   |                                      |   |   |                                      |
| Cilazapril  |                                      |   |   |                                      |
| Cimetidine  |                                      | (a) For the short-term symptomatic relief of heartburn, dyspepsia, indigestion, acid indigestion and hyperacidity and for the prophylaxis of meal-induced heartburn<br><br>(b) For the prophylactic management of nocturnal heartburn by a single | (a) 200mg (MD)<br>800mg (MDD)<br>For a maximum period of 14 days<br><br>(b) 100mg (MD) to be taken as a single dose at night<br>For a maximum period of 14 days |                                      |

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|---|---|---|---|--------------------------------------|
| <i>Column 1<br/>Substance</i>   | <i>Column 2<br/>Maximum strength</i>      | <i>Column 3<br/>Route of administration, use or pharmaceutical form</i> | <i>Column 4<br/>Treatment limitations</i> | <i>Column 5<br/>Maximum quantity</i> |
|   |   | dose taken at night   |   |                                      |
| Cimetidine Hydrochloride  |   |   |   |                                      |
| Cinchocaine   | 3.0 per cent                              | Non-ophthalmic use  |   |                                      |
| Cinchocaine Hydrochloride   | Equivalent of 3.0 per cent of Cinchocaine | Non-ophthalmic use  |   |                                      |
| Cinchophen  |   |   |   |                                      |
| Cinoxacin   |   |   |   |                                      |
| Ciprofibrate  |   |   |   |                                      |
| Ciprofloxacin   |   |   |   |                                      |
| Ciprofloxacin Hydrochloride   |   |   |   |                                      |
| Cisapride   |   |   |   |                                      |
| Cisplatin   |   |   |   |                                      |
| [ <sup>194</sup> F]Citalopram Hydrobromide]   |   |   |   |                                      |
| Clarithromycin  |   |   |   |                                      |
| Clavulanic Acid   |   |   |   |                                      |
| Clidinium Bromide   |   |   |   |                                      |
| Clindamycin   |   |   |   |                                      |
| Clindamycin Hydrochloride   |   |   |   |                                      |
| Clindamycin Palmitate Hydrochloride   |   |   |   |                                      |
| Clindamycin Phosphate   |   |   |   |                                      |

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|---|--------------------------------------|---|---|---|
| <i>Column 1<br/>Substance</i>   | <i>Column 2<br/>Maximum strength</i> | <i>Column 3<br/>Route of administration, use or pharmaceutical form</i>   | <i>Column 4<br/>Treatment limitations</i> | <i>Column 5<br/>Maximum quantity</i>  |
| Clioquinol  | (2) 35mg                             | (1) External (other than treatment of mouth ulcers)<br><br>(2) Treatment of mouth ulcers  | (2) 350mg (MDD)                           |   |
| Clobetasol Propionate   |                                      |   |   |   |
| Clobetasone Butyrate  | [ <sup>F212</sup> 0.05 per cent]     | [ <sup>F212</sup> Cream for use in adults and in children aged 12 years and over, for external use for the short term symptomatic treatment and control of patches of eczema and dermatitis (excluding seborrhoeic dermatitis)] |   | [ <sup>F212</sup> Container or package containing not more than 15g of medicinal product] |
| Clofazimine   |                                      |   |   |   |
| Clofibrate  |                                      |   |   |   |
| Clomiphene Citrate  |                                      |   |   |   |
| Clomipramine  |                                      |   |   |   |
| Clomipramine Hydrochloride  |                                      |   |   |   |
| Clomocycline  |                                      |   |   |   |

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|---|--|--|---|--|
| <i>Column 1<br/>Substance</i>   | <i>Column 2<br/>Maximum<br/>strength</i> | <i>Column 3<br/>Route of<br/>administration,<br/>use or<br/>pharmaceutical<br/>form</i>                                    | <i>Column 4<br/>Treatment limitations</i> | <i>Column 5<br/>Maximum<br/>quantity</i> |
| Clomocycline<br>Sodium  |  |  |   |  |
| Clonidine   |  |  |   |  |
| Clonidine<br>Hydrochloride  |  |  |   |  |
| Clopamide   |  |  |   |  |
| Clopenthixol<br>Decanoate   |  |  |   |  |
| Clopenthixol<br>Hydrochloride   |  |  |   |  |
| Clorexolone   |  |  |   |  |
| Clotrimazole  |  | External but<br>in the case<br>of vaginal<br>use only<br>external<br>use for the<br>treatment<br>of vaginal<br>candidiasis |   |  |
| Cloxacillin<br>Benzathine   |  |  |   |  |
| Cloxacillin<br>Sodium   |  |  |   |  |
| Clozapine   |  |  |   |  |
| Cocculus<br>Indicus   |  |  |   |  |
| Co-<br>dergocrine<br>Mesylate   |  |  |   |  |
| Colaspase   |  |  |   |  |
| Colchicine  |  |  |   |  |
| Colestipol<br>Hydrochloride   |  |  |   |  |
| Colfosceril<br>Palmitate  |  |  |   |  |



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| <i>Exemptions from the restrictions on the sale and supply of prescription only medicines</i> |  |   |   |  |
|---|--|---|---|--|
| <i>Column 1<br/>Substance</i>   | <i>Column 2<br/>Maximum<br/>strength</i> | <i>Column 3<br/>Route of<br/>administration,<br/>use or<br/>pharmaceutical<br/>form</i> | <i>Column 4<br/>Treatment limitations</i> | <i>Column 5<br/>Maximum<br/>quantity</i> |
| Colistin Sulphate   |  |   |   |  |
| Colistin Sulphomethate  |  |   |   |  |
| Colistin Sulphomethate Sodium   |  |   |   |  |
| Coniine   |  |   |   |  |
| Conium Leaf   | 7.0 per cent                             | External  |   |  |
| Corticotrophin  |  |   |   |  |
| Cortisone   |  |   |   |  |
| Cortisone Acetate   |  |   |   |  |
| Co-tetroxazine  |  |   |   |  |
| Co-trimoxazole  |  |   |   |  |
| Cropropamide  |  |   |   |  |
| Crotethamide  |  |   |   |  |
| Croton Oil  |  |   |   |  |
| Croton Seed   |  |   |   |  |
| Curare  |  |   |   |  |
| Cyclofenil  |  |   |   |  |
| Cyclopenthiiazide   |  |   |   |  |
| Cyclopentolate Hydrochloride  |  |   |   |  |
| Cyclophosphamide  |  |   |   |  |
| Cycloserine   |  |   |   |  |
| Cyclosporin   |  |   |   |  |
| Cyclothiazide   |  |   |   |  |
| Cyproterone Acetate   |  |   |   |  |

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|---|--|---|---|--|
| <i>Column 1<br/>Substance</i>   | <i>Column 2<br/>Maximum<br/>strength</i> | <i>Column 3<br/>Route of<br/>administration,<br/>use or<br/>pharmaceutical<br/>form</i> | <i>Column 4<br/>Treatment limitations</i> | <i>Column 5<br/>Maximum<br/>quantity</i> |
| Cytarabine  |  |   |   |  |
| Cytarabine<br>Hydrochloride   |  |   |   |  |
| Dacarbazine   |  |   |   |  |
| Dalteparin<br>Sodium  |  |   |   |  |
| Danazol   |  |   |   |  |
| Danthron  |  |   |   |  |
| Dantrolene<br>Sodium  |  |   |   |  |
| Dapsone   |  |   |   |  |
| Dapsone<br>Ethane<br>Ortho<br>Sulphonate  |  |   |   |  |
| Daunorubicin<br>Hydrochloride   |  |   |   |  |
| Deanol<br>Bitartrate  |  |   | 26mg (MDD)                                |  |
| Debrisoquine<br>Sulphate  |  |   |   |  |
| Demecarium<br>Bromide   |  |   |   |  |
| Demeclocycline  |  |   |   |  |
| Demeclocycline<br>Calcium   |  |   |   |  |
| Demeclocycline<br>Hydrochloride   |  |   |   |  |
| Deoxycortone<br>Acetate   |  |   |   |  |
| Deoxycortone<br>Pivalate  |  |   |   |  |
| Deptropine<br>Citrate   |  |   |   |  |



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|---|--------------------------------------|---|---|--|
| <i>Column 1<br/>Substance</i>   | <i>Column 2<br/>Maximum strength</i> | <i>Column 3<br/>Route of administration, use or pharmaceutical form</i>   | <i>Column 4<br/>Treatment limitations</i>   | <i>Column 5<br/>Maximum quantity</i>                                   |
| Dexamethasone<br>Troxundate   |                                      |   |   |  |
| Dexfenfluramine<br>Hydrochloride  |                                      |   |   |  |
| Dextromethorphan<br>Hydrobromide  |                                      | Internal  | (a) In the case of a prolonged release preparation:<br>equivalent of 30mg of Dextromethorphan (MD)<br><br>equivalent of 75mg of Dextromethorphan (MDD)<br><br>(b) in any other case:<br>equivalent of 15mg of Dextromethorphan (MD)<br><br>equivalent of 75mg of Dextromethorphan (MDD) |  |
| Dextrothyroxine<br>Sodium   |                                      |   |   |  |
| Diazoxide   |                                      |   |   |  |
| Dibenzepin<br>Hydrochloride   |                                      |   |   |  |
| Dichloralphenazone  |                                      |   |   |  |
| Dichlorphenamide  |                                      |   |   |  |
| Diclofenac<br>Diethylammonium   | 1.16 per cent                        | External<br><br>For local symptomatic relief of pain and inflammation in trauma of the tendons, ligaments, muscles and joints and in localised forms of | For maximum period of 7 days  | Container or package containing not more than 30g of medicinal product |

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|---|--------------------------------------|---|---|--------------------------------------|
| <i>Column 1<br/>Substance</i>   | <i>Column 2<br/>Maximum strength</i> | <i>Column 3<br/>Route of administration, use or pharmaceutical form</i> | <i>Column 4<br/>Treatment limitations</i> | <i>Column 5<br/>Maximum quantity</i> |
|   |                                      | soft tissue rheumatism  |   |                                      |
|   |                                      | For use in adults and children not less than 12 years                   |   |                                      |
| Diclofenac Potassium  |                                      |   |   |                                      |
| Diclofenac Sodium   |                                      |   |   |                                      |
| Dicyclomine Hydrochloride   |                                      |   | 10mg (MD)<br>60mg (MDD)                   |                                      |
| [ <sup>193</sup> F]Didanosine]  |                                      |   |   |                                      |
| Dienoestrol   |                                      |   |   |                                      |
| Diethanolamine Fusidate   |                                      |   |   |                                      |
| Diflucortolone Valerate   |                                      |   |   |                                      |
| Diflunisal  |                                      |   |   |                                      |
| Digitalin   |                                      |   |   |                                      |
| Digitalis Leaf  |                                      |   |   |                                      |
| Digitalis Prepared  |                                      |   |   |                                      |
| Digitoxin   |                                      |   |   |                                      |
| Digoxin   |                                      |   |   |                                      |
| Dihydralazine Sulphate  |                                      |   |   |                                      |
| Dihydroergotamine Mesylate  |                                      |   |   |                                      |
| Dihydrostreptomycin   |                                      |   |   |                                      |
| Dihydrostreptomycin Sulphate  |                                      |   |   |                                      |

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|---|---|--|---|---|
| <i>Column 1<br/>Substance</i>   | <i>Column 2<br/>Maximum strength</i>            | <i>Column 3<br/>Route of administration, use or pharmaceutical form</i>                                | <i>Column 4<br/>Treatment limitations</i> | <i>Column 5<br/>Maximum quantity</i>  |
| Diloxanide Furoate  |   |  |   |   |
| Diltiazem Hydrochloride   |   |  |   |   |
| Dimercaprol   |   |  |   |   |
| Dimethisoquin Hydrochloride   |   | Non-ophthalmic use   |   |   |
| Dimethisterone  |   |  |   |   |
| Dimethothiazine Mesylate  |   |  |   |   |
| Dimethyl Sulphoxide   |   |  |   |   |
| Dimethyltubocurarine Bromide  |   |  |   |   |
| Dimethyltubocurarine Chloride   |   |  |   |   |
| Dimethyltubocurarine Iodide   |   |  |   |   |
| Dinoprost   |   |  |   |   |
| Dinoprost Trometamol  |   |  |   |   |
| Dinoprostone  |   |  |   |   |
| [ <sup>F196</sup> Diphenhydramine Hydrochloride]  | All preparations except liquid-filled capsules] |  |   |   |
| [ <sup>F213</sup> Diphenoxylate Hydrochloride]  | [ <sup>F213</sup> 2.5 mg]                       | [ <sup>F213</sup> In combination with Atropine Sulphate for short term use as an adjunctive therapy to | [ <sup>F213</sup> 25 mg (MDD)]            | [ <sup>F213</sup> Container or package containing not more than 20 tablets] |

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|---|--------------------------------------|--|---|---|
| <i>Column 1<br/>Substance</i>   | <i>Column 2<br/>Maximum strength</i> | <i>Column 3<br/>Route of administration, use or pharmaceutical form</i>                              | <i>Column 4<br/>Treatment limitations</i>   | <i>Column 5<br/>Maximum quantity</i>  |
|   |                                      | appropriate rehydration in acute diarrhoea   |   |   |
|   |                                      | For use in persons aged 16 years and over  |   |   |
|   |                                      | Tablets]   |   |   |
| Dipivefrin Hydrochloride  |                                      |  |   |   |
| Dipyridamole  |                                      |  |   |   |
| Disodium Etidronate   |                                      |  |   |   |
| Disodium Pamidronate  |                                      |  |   |   |
| Disopyramide  |                                      |  |   |   |
| Disopyramide Phosphate  |                                      |  |   |   |
| Distigmine Bromide  |                                      |  |   |   |
| Disulfiram  |                                      |  |   |   |
| Dithranol   | 1.0 per cent                         |  |   |   |
| Dobutamine Hydrochloride  |                                      |  |   |   |
| [ <sup>F213</sup> Dolasetron Mesilate]  |                                      |  |   |   |
| Domperidone   |                                      | [ <sup>F214</sup> For the relief of post-prandial symptoms of excessive fullness, nausea, epigastric | [ <sup>F214</sup> 10mg of Domperidone (MD)]<br>[ <sup>F214</sup> 40mg of Domperidone (MDD)] | [ <sup>F214</sup> Container or package containing not more than 200mg of Domperidone] |

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|---|--------------------------------------|---|---|--|
| <i>Column 1<br/>Substance</i>   | <i>Column 2<br/>Maximum strength</i> | <i>Column 3<br/>Route of administration, use or pharmaceutical form</i>   | <i>Column 4<br/>Treatment limitations</i>   | <i>Column 5<br/>Maximum quantity</i>   |
|   |                                      | bloating and belching, occasionally accompanied by epigastric discomfort and heartburn]   |   |  |
| Domperidone Maleate   |                                      | [ <sup>F215</sup> For the relief of post-prandial symptoms of excessive fullness, nausea, epigastric bloating and belching, occasionally accompanied by epigastric discomfort and heartburn,] | [ <sup>F216</sup> 10 mg of Domperidone as Domperidone Maleate (MD)]<br>[ <sup>F216</sup> 40 mg of Domperidone as Domperidone Maleate (MDD)] | [ <sup>F215</sup> Container or package containing not more than [ <sup>F217</sup> 200mg] of Domperidone as Domperidone Maleate;] |
| [ <sup>F197</sup> Donepezil Hydrochloride]  |                                      |   |   |  |
| Dopamine Hydrochloride  |                                      |   |   |  |
| Dopexamine Hydrochloride  |                                      |   |   |  |
| [ <sup>F194</sup> Dorzolamide Hydrochloride]  |                                      |   |   |  |
| Dothiepin   |                                      |   |   |  |
| Dothiepin Hydrochloride   |                                      |   |   |  |
| Doxapram Hydrochloride  |                                      |   |   |  |



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|---|--------------------------------------|--|---|--------------------------------------|
| <i>Column 1<br/>Substance</i>   | <i>Column 2<br/>Maximum strength</i> | <i>Column 3<br/>Route of administration, use or pharmaceutical form</i>                            | <i>Column 4<br/>Treatment limitations</i> | <i>Column 5<br/>Maximum quantity</i> |
| Doxazosin Mesylate  |                                      |  |   |                                      |
| Doxepin Hydrochloride   |                                      |  |   |                                      |
| Doxorubicin   |                                      |  |   |                                      |
| Doxorubicin Hydrochloride   |                                      |  |   |                                      |
| Doxycycline   |                                      |  |   |                                      |
| Doxycycline Calcium Chelate   |                                      |  |   |                                      |
| Doxycycline Hydrochloride   |                                      |  |   |                                      |
| Droperidol  |                                      |  |   |                                      |
| Dydrogesterone  |                                      |  |   |                                      |
| Dyflos  |                                      |  |   |                                      |
| Econazole   |                                      | External but in the case of vaginal use only external use for the treatment of vaginal candidiasis |   |                                      |
| Econazole Nitrate   |                                      | External but in the case of vaginal use only external use for the treatment of vaginal candidiasis |   |                                      |
| Ecothiopate Iodide  |                                      |  |   |                                      |
| Edrophonium Chloride  |                                      |  |   |                                      |

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|---|---------------------------------------|---|---|--------------------------------------|
| <i>Column 1<br/>Substance</i>   | <i>Column 2<br/>Maximum strength</i>  | <i>Column 3<br/>Route of administration, use or pharmaceutical form</i> | <i>Column 4<br/>Treatment limitations</i> | <i>Column 5<br/>Maximum quantity</i> |
| Eflornithine Hydrochloride  |                                       |   |   |                                      |
| [ <sup>193</sup> F]Eformoterol Fumarate]  |                                       |   |   |                                      |
| Embutramide   |                                       |   |   |                                      |
| Emepronium Bromide  |                                       |   |   |                                      |
| Emetine   | 1.0 per cent                          |   |   |                                      |
| Emetine Bismuth Iodide  |                                       |   |   |                                      |
| Emetine Hydrochloride   | Equivalent of 1.0 per cent of Emetine |   |   |                                      |
| Enalapril Maleate   |                                       |   |   |                                      |
| Encephalitis Virus, Tick-borne, Cent Eur  |                                       |   |   |                                      |
| Enoxacin  |                                       |   |   |                                      |
| Enoxaparin Sodium   |                                       |   |   |                                      |
| Enoximone   |                                       |   |   |                                      |
| Ephedrine   |                                       | (1) Internal (other than nasal sprays or nasal drops)                   | (1) 30mg (MD)                             |                                      |
|   |                                       |   | 60mg (MDD)                                |                                      |
|   | (2) 2.0 per cent                      | (2) Nasal sprays or nasal drops   |   |                                      |
|   |                                       | (3) External  |   |                                      |

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|---|--|--|---|--------------------------------------|
| <i>Column 1<br/>Substance</i>   | <i>Column 2<br/>Maximum strength</i>           | <i>Column 3<br/>Route of administration, use or pharmaceutical form</i>  | <i>Column 4<br/>Treatment limitations</i>   | <i>Column 5<br/>Maximum quantity</i> |
| Ephedrine Hydrochloride   | (1)<br>Equivalent of 2.0 per cent of Ephedrine | (1) Internal (other than nasal sprays or nasal drops)<br><br>(2) Nasal sprays or nasal drops                     | (1) Equivalent of 30mg of Ephedrine (MD)<br><br>Equivalent of 60mg of Ephedrine (MDD)         |                                      |
| Ephedrine Sulphate  | (2)<br>Equivalent of 2.0 per cent of Ephedrine | (1) Internal (other than nasal sprays or nasal drops)<br><br>(2) Nasal sprays or nasal drops<br><br>(3) External | (1) Equivalent of 30mg of Ephedrine (MD)<br><br><br><br>Equivalent of 60mg of Ephedrine (MDD) |                                      |
| Epicillin   |  |  |   |                                      |
| Epirubicin  |  |  |   |                                      |
| Epirubicin Hydrochloride  |  |  |   |                                      |
| Epithiazide   |  |  |   |                                      |
| Epoetin Alfa  |  |  |   |                                      |
| Epoetin Beta  |  |  |   |                                      |
| Epoprostenol Sodium   |  |  |   |                                      |
| Ergometrine Maleate   |  |  |   |                                      |

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|---|--|---|---|--|
| <i>Column 1<br/>Substance</i>   | <i>Column 2<br/>Maximum<br/>strength</i> | <i>Column 3<br/>Route of<br/>administration,<br/>use or<br/>pharmaceutical<br/>form</i> | <i>Column 4<br/>Treatment limitations</i> | <i>Column 5<br/>Maximum<br/>quantity</i> |
| Ergometrine<br>Tartrate   |  |   |   |  |
| Ergot,<br>Prepared  |  |   |   |  |
| Ergotamine<br>Tartrate  |  |   |   |  |
| Erythromycin  |  |   |   |  |
| Erythromycin<br>Estolate  |  |   |   |  |
| Erythromycin<br>Ethylcarbonate  |  |   |   |  |
| Erythromycin<br>Ethyl<br>Succinate  |  |   |   |  |
| Erythromycin<br>Lactobionate  |  |   |   |  |
| Erythromycin<br>Phosphate   |  |   |   |  |
| Erythromycin<br>Stearate  |  |   |   |  |
| Erythromycin<br>Thiocyanate   |  |   |   |  |
| Esmolol<br>Hydrochloride  |  |   |   |  |
| Estramustine<br>Phosphate   |  |   |   |  |
| [ <sup>218</sup> F]Estramustine<br>Sodium<br>Phosphate]                                       |  |   |   |  |
| Etafedrine<br>Hydrochloride   |  |   |   |  |
| Ethacrynic<br>Acid  |  |   |   |  |
| Ethambutol<br>Hydrochloride   |  |   |   |  |

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|---|--|---|---|--|
| <i>Column 1<br/>Substance</i>   | <i>Column 2<br/>Maximum<br/>strength</i> | <i>Column 3<br/>Route of<br/>administration,<br/>use or<br/>pharmaceutical<br/>form</i>       | <i>Column 4<br/>Treatment limitations</i>                   | <i>Column 5<br/>Maximum<br/>quantity</i> |
| Ethamivan   |  |   |   |  |
| Ethamsylate   |  |   |   |  |
| Ethiazide   |  |   |   |  |
| Ethinyl<br>Androstenediol   |  |   |   |  |
| Ethinylestradiol  |  |   |   |  |
| Ethionamide   |  |   |   |  |
| Ethisterone   |  |   |   |  |
| Ethoglucid  |  |   |   |  |
| Ethoheptazine<br>Citrate  |  |   |   |  |
| Ethopropazine<br>Hydrochloride  |  |   |   |  |
| Ethosuximide  |  |   |   |  |
| Ethotoin  |  |   |   |  |
| Ethyl<br>Biscoumacetate   |  |   |   |  |
| Ethinodiol<br>Diacetate   |  |   |   |  |
| Etodolac  |  |   |   |  |
| Etomidate   |  |   |   |  |
| Etomidate<br>Hydrochloride  |  |   |   |  |
| Etoposide   |  |   |   |  |
| Etretinate  |  |   |   |  |
| [ <sup>194</sup> F]Exemestane]  |  |   |   |  |
| Famciclovir   |  |   |   |  |
| Famotidine  |  | For the<br>short-term<br>symptomatic<br>relief of<br>heartburn,<br>dyspepsia,<br>indigestion, | 10mg (MD)<br>20mg (MDD)<br>For maximum period of<br>14 days |  |

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|---|--------------------------------------|---|---|---|
| <i>Column 1<br/>Substance</i>   | <i>Column 2<br/>Maximum strength</i> | <i>Column 3<br/>Route of administration, use or pharmaceutical form</i>   | <i>Column 4<br/>Treatment limitations</i> | <i>Column 5<br/>Maximum quantity</i>  |
|   |                                      | acid indigestion and hyperacidity, and prevention of these symptoms when associated with food and drink, including nocturnal symptoms   |   |   |
| Fazadinium Bromide  |                                      |   |   |   |
| Felbinac  | 3.17 per cent                        | External<br>[ <sup>F220</sup> For the relief of rheumatic pain, pain of non-serious arthritic conditions and soft tissue injuries such as sprains, strains and contusions]<br><br>For use in adults and children not less than 12 years | For maximum period of 7 days              | Container or package containing not more than [ <sup>F219</sup> 50g] of medicinal product |
| Felodipine  |                                      |   |   |   |
| Felypressin   |                                      |   |   |   |
| Fenbufen  |                                      |   |   |   |
| Fenclofenac   |                                      |   |   |   |

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|---|--|--|---|--|
| <i>Column 1<br/>Substance</i>   | <i>Column 2<br/>Maximum<br/>strength</i> | <i>Column 3<br/>Route of<br/>administration,<br/>use or<br/>pharmaceutical<br/>form</i>  | <i>Column 4<br/>Treatment limitations</i> | <i>Column 5<br/>Maximum<br/>quantity</i> |
| Fenfluramine<br>Hydrochloride   |  |  |   |  |
| Fenofibrate   |  |  |   |  |
| Fenoprofen  |  |  |   |  |
| Fenoprofen<br>Calcium   |  |  |   |  |
| Fenoterol<br>Hydrobromide   |  |  |   |  |
| Fenticonazole<br>Nitrate  |  | [ <sup>F212</sup> External<br>use (but in<br>the case of<br>vaginal use,<br>only for the<br>treatment<br>of vaginal<br>candidiasis)] |   |  |
| Feprazone   |  |  |   |  |
| Ferrous<br>Arsenate   |  |  |   |  |
| [ <sup>F194</sup> Ferumoxsil]   |  |  |   |  |
| [ <sup>F197</sup> Fexofenadine<br>Hydrochloride]  |  |  |   |  |
| Filgrastim  |  |  |   |  |
| Finasteride   |  |  |   |  |
| Flavoxate<br>Hydrochloride  |  |  |   |  |
| Flecainide<br>Acetate   |  |  |   |  |
| Flosequinan   |  |  |   |  |
| Fluanisone  |  |  |   |  |
| Flubendazole  |  |  |   |  |
| Fluclorolone<br>Acetonide   |  |  |   |  |
| Flucloxacillin<br>Magnesium   |  |  |   |  |

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|---|--------------------------------------|--|---|---|
| <i>Column 1<br/>Substance</i>   | <i>Column 2<br/>Maximum strength</i> | <i>Column 3<br/>Route of administration, use or pharmaceutical form</i>  | <i>Column 4<br/>Treatment limitations</i>   | <i>Column 5<br/>Maximum quantity</i>                                      |
| Flucloxacillin Sodium   |                                      |  |   |   |
| Fluconazole   |                                      | For oral administration for the treatment of vaginal candidiasis [ <sup>F221</sup> or associated candidal balanitis] in persons aged not less than 16 but less than 60 years | 150mg (MD)  | Container or package containing not more than 150mg of Fluconazole        |
| Flucytosine   |                                      |  |   |   |
| Fludrocortisone Acetate   |                                      |  |   |   |
| Flufenamic Acid   |                                      |  |   |   |
| Flumazenil  |                                      |  |   |   |
| Flumethasone  |                                      |  |   |   |
| Flumethasone Pivalate   |                                      |  |   |   |
| Flunisolide   | 0.025 per cent                       | (a) For the prevention and treatment of seasonal allergic rhinitis, including hay fever<br><br>[ <sup>F222</sup> For use in persons aged 18                                  | (a) 50mcg per nostril (MD)<br>100mcg per nostril (MDD)<br><br>[ <sup>F223</sup> For a maximum period of 3 months] | (a) Container or package containing not more than 6,000mcg of Flunisolide |



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|---|--------------------------------------|---|---|--------------------------------------|
| <i>Column 1<br/>Substance</i>   | <i>Column 2<br/>Maximum strength</i> | <i>Column 3<br/>Route of administration, use or pharmaceutical form</i> | <i>Column 4<br/>Treatment limitations</i> | <i>Column 5<br/>Maximum quantity</i> |
|   |                                      | years and over]   |   |                                      |
|   |                                      | In the form of a non-pressurised nasal spray                            |   |                                      |
|   | F224                                 | F224  | F224                                      | F224                                 |
|   | ...                                  | ...   | ...                                       | ...                                  |
|   |                                      | F224  |   |                                      |
|   |                                      | ...   |   |                                      |
|   | F224                                 |   |   |                                      |
|   | ...                                  |   |   |                                      |
|   | F224                                 |   |   |                                      |
|   | ...                                  |   |   |                                      |
| Fluocinolone Acetonide  |                                      |   |   |                                      |
| Fluocinonide  |                                      |   |   |                                      |
| Fluocortin Butyl  |                                      |   |   |                                      |
| Fluocortolone   |                                      |   |   |                                      |
| Fluocortolone Hexanoate   |                                      |   |   |                                      |
| Fluocortolone Pivalate  |                                      |   |   |                                      |
| Fluorescein Dilaurate   |                                      |   |   |                                      |
| Fluorometholone   |                                      |   |   |                                      |
| Fluorouracil  |                                      |   |   |                                      |
| Fluorouracil Trometamol   |                                      |   |   |                                      |
| Fluoxetine Hydrochloride  |                                      |   |   |                                      |
| Flupenthixol Decanoate  |                                      |   |   |                                      |

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| <i>Exemptions from the restrictions on the sale and supply of prescription only medicines</i> |                                      |   |   |   |
|---|--------------------------------------|---|---|---|
| <i>Column 1<br/>Substance</i>   | <i>Column 2<br/>Maximum strength</i> | <i>Column 3<br/>Route of administration, use or pharmaceutical form</i> | <i>Column 4<br/>Treatment limitations</i> | <i>Column 5<br/>Maximum quantity</i>  |
| Flupenthixol Hydrochloride  |                                      |   |   |   |
| Fluperolone Acetate   |                                      |   |   |   |
| Fluphenazine Decanoate  |                                      |   |   |   |
| Fluphenazine Enanthate  |                                      |   |   |   |
| Fluphenazine Hydrochloride  |                                      |   |   |   |
| Fluprednidene Acetate   |                                      |   |   |   |
| Fluprednisolone   |                                      |   |   |   |
| Fluprostenol Sodium   |                                      |   |   |   |
| Flurandrenolone   |                                      |   |   |   |
| Flurbiprofen  | [ <sup>F225</sup> 8.75 mg]           | [ <sup>F226</sup> Throat lozenges]                                      | [ <sup>F227</sup> 43.75 mg (MDD)]         | [ <sup>F228</sup> Container or package containing not more than 140 mg of Flurbiprofen] |
| Flurbiprofen Sodium   |                                      |   |   |   |
| Fluspirilene  |                                      |   |   |   |
| Flutamide   |                                      |   |   |   |
| Fluticasone Propionate  |                                      |   |   |   |
| [ <sup>F197</sup> Flutrimazole]   |                                      |   |   |   |
| Fluvastatin Sodium  |                                      |   |   |   |
| Fluvoxamine Maleate   |                                      |   |   |   |
| Folic Acid  |                                      |   | 500mcg (MDD)                              |   |

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|---|--------------------------------------|---|---|--------------------------------------|
| <i>Column 1<br/>Substance</i>   | <i>Column 2<br/>Maximum strength</i> | <i>Column 3<br/>Route of administration, use or pharmaceutical form</i> | <i>Column 4<br/>Treatment limitations</i> | <i>Column 5<br/>Maximum quantity</i> |
| Formestane  |                                      |   |   |                                      |
| Formocortol   |                                      |   |   |                                      |
| Foscarnet Sodium  |                                      |   |   |                                      |
| Fosfestrol Sodium   |                                      |   |   |                                      |
| Fosfomycin Trometamol   |                                      |   |   |                                      |
| Fosinopril Sodium   |                                      |   |   |                                      |
| Framycetin Sulphate   |                                      |   |   |                                      |
| Frusemide   |                                      |   |   |                                      |
| Furazolidone  |                                      |   |   |                                      |
| Fusafungine   |                                      |   |   |                                      |
| Fusidic Acid  |                                      |   |   |                                      |
| Gabapentin  |                                      |   |   |                                      |
| Gadoteridol   |                                      |   |   |                                      |
| Gallamine Triethiodide  |                                      |   |   |                                      |
| Ganciclovir Sodium  |                                      |   |   |                                      |
| Gelsemine   | 0.1 per cent                         |   |   |                                      |
| Gelsemium   |                                      |   | 25mg (MD)<br>75mg (MDD)                   |                                      |
| Gemeprost   |                                      |   |   |                                      |
| Gemfibrozil   |                                      |   |   |                                      |
| Gentamicin Sulphate   |                                      |   |   |                                      |
| Gestodene   |                                      |   |   |                                      |

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| <i>Exemptions from the restrictions on the sale and supply of prescription only medicines</i> |                                      |   |   |                                      |
|---|--------------------------------------|---|---|--------------------------------------|
| <i>Column 1<br/>Substance</i>   | <i>Column 2<br/>Maximum strength</i> | <i>Column 3<br/>Route of administration,<br/>use or pharmaceutical form</i> | <i>Column 4<br/>Treatment limitations</i> | <i>Column 5<br/>Maximum quantity</i> |
| Gestrinone  |                                      |   |   |                                      |
| Gestronol   |                                      |   |   |                                      |
| Gestronol Hexanoate   |                                      |   |   |                                      |
| Glibenclamide   |                                      |   |   |                                      |
| Glibornuride  |                                      |   |   |                                      |
| Gliclazide  |                                      |   |   |                                      |
| Glipizide   |                                      |   |   |                                      |
| Gliquidone  |                                      |   |   |                                      |
| Glisoxepide   |                                      |   |   |                                      |
| Glucagon  |                                      |   |   |                                      |
| Glycopyrronium Bromide  |                                      |   | 1mg (MD)<br>2mg (MDD)                     |                                      |
| Glymidine   |                                      |   |   |                                      |
| Gonadorelin   |                                      |   |   |                                      |
| Goserelin Acetate   |                                      |   |   |                                      |
| Gramicidin  | 0.2 per cent                         | External  |   |                                      |
| Granisetron Hydrochloride   |                                      |   |   |                                      |
| Griseofulvin  |                                      |   |   |                                      |
| Growth Hormone  |                                      |   |   |                                      |
| Guanethidine Monosulphate   |                                      |   |   |                                      |
| Guanfacine Hydrochloride  |                                      |   |   |                                      |
| Guanoclor Sulphate  |                                      |   |   |                                      |
| Guanoxan Sulphate   |                                      |   |   |                                      |
| Halcinonide   |                                      |   |   |                                      |

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|---|--|---|---|--|
| <i>Column 1<br/>Substance</i>   | <i>Column 2<br/>Maximum<br/>strength</i> | <i>Column 3<br/>Route of<br/>administration,<br/>use or<br/>pharmaceutical<br/>form</i> | <i>Column 4<br/>Treatment limitations</i> | <i>Column 5<br/>Maximum<br/>quantity</i> |
| Halofantrine<br>Hydrochloride   |  |   |   |  |
| Haloperidol   |  |   |   |  |
| Haloperidol<br>Decanoate  |  |   |   |  |
| Heparin   |  | External  |   |  |
| Heparin<br>Calcium  |  | External  |   |  |
| Heparin<br>Sodium   |  |   |   |  |
| Hexachlorophane   |  | External  |   |  |
|   | (a) 2.0 per cent                         | (a) Soaps   |   |  |
|   | (b) 0.1 per cent                         | (b) Aerosols  |   |  |
|   | (c) 0.75 per cent                        | (c) preparations other than soaps and aerosols  |   |  |
| Hexamine<br>Phenylcinchoninate  |  |   |   |  |
| Hexobarbitone   |  |   |   |  |
| Hexobarbitone<br>Sodium   |  |   |   |  |
| Hexoestrol  |  |   |   |  |
| Hexoestrol<br>Dipropionate  |  |   |   |  |
| L-Histidine<br>Hydrochloride  |  | Dietary<br>supplementation  |   |  |
| Homatropine   |  | (1) Internal  | (1) 0.15mg (MD)<br>0.45mg (MDD)           |  |
|   |  | (2) External<br>(except<br>ophthalmic)  |   |  |

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|---|--------------------------------------|--|---|---|
| <i>Column 1<br/>Substance</i>   | <i>Column 2<br/>Maximum strength</i> | <i>Column 3<br/>Route of administration, use or pharmaceutical form</i>  | <i>Column 4<br/>Treatment limitations</i> | <i>Column 5<br/>Maximum quantity</i>  |
| Homatropine Hydrobromide  |                                      |  | 0.2mg (MD)                                |   |
|   |                                      |  | 0.6mg (MDD)                               |   |
| Homatropine Methylbromide   |                                      |  | 2mg (MD)                                  |   |
|   |                                      |  | 6mg (MDD)                                 |   |
| Hydralazine Hydrochloride   |                                      |  |   |   |
| Hydrargaphen  |                                      | Local application to skin  |   |   |
| Hydrobromic Acid  |                                      |  |   |   |
| Hydrochlorothiazide   |                                      |  |   |   |
| Hydrocortisone  | [ <sup>F229</sup> (1)0.5 per cent]   | [ <sup>F229</sup> (1) External (a) For use in combination with Nystatin of maximum strength 3.0 per cent for intertrigo (b) For use in adults and children not less than 10 years] |   | [ <sup>F229</sup> (1) Container or package containing not more than 15g of medicinal product] |
|   | [ <sup>F230</sup> (2)1.0 per cent]   | [ <sup>F230</sup> (2) External (a) For use either alone  |   | [ <sup>F230</sup> (2) Container or package containing not more than 15g                       |

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|---|--|---|---|--|
| <i>Column 1<br/>Substance</i>   | <i>Column 2<br/>Maximum<br/>strength</i> | <i>Column 3<br/>Route of<br/>administration,<br/>use or<br/>pharmaceutical<br/>form</i>   | <i>Column 4<br/>Treatment limitations</i> | <i>Column 5<br/>Maximum<br/>quantity</i>                             |
|   |  | or in<br>conjunction<br>with<br>Crotamiton<br>in<br>irritant<br>dermatitis,<br>contact<br>allergic<br>dermatitis,<br>insect<br>bite<br>reactions,<br>mild<br>to<br>moderate<br>eczema,<br>and<br>either<br>in<br>combination<br>with<br>Clotrimazole<br>[ <sup>231</sup> F <sup>231</sup> or<br>Miconazole<br>Nitrate]<br>for<br>athlete's<br>foot<br>and<br>candidal<br>intertrigo<br>or in<br>combination<br>with<br>lignocaine<br>for<br>anal<br>and<br>perianal<br>itch<br>associated<br>with<br>haemorrhoids |   | of medicinal<br>product<br>(cream or<br>ointment) or<br>30ml (spray) |

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|---|--|--|---|---|
| <i>Column 1<br/>Substance</i>   | <i>Column 2<br/>Maximum strength</i>     | <i>Column 3<br/>Route of administration, use or pharmaceutical form</i>  | <i>Column 4<br/>Treatment limitations</i> | <i>Column 5<br/>Maximum quantity</i>  |
|   |  | (b) For use in adults and children not less than 10 years  |   |   |
|   |  | (c) Cream ointment or spray  |   |   |
| Hydrocortison Acetate   | Equivalent to 1.0 per cent Hydrocortison | External For use in irritant dermatitis, contact allergic dermatitis, insect bite reactions, mild to moderate eczema, and in combination with one or more of the following:<br>Benzyl Benzoate,<br>Bismuth Oxide,<br>Bismuth Subgallate,<br>Peru Balsam,<br>Pramoxine Hydrochloride,<br>Zinc Oxide, for haemorrhoids |   | Container or package containing not more than 15g of medicinal product<br><br>In the case of suppositories, container or package containing no more than 12 |



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| <i>Exemptions from the restrictions on the sale and supply of prescription only medicines</i> |                                      |  |   |  |
|---|--------------------------------------|--|---|--|
| <i>Column 1<br/>Substance</i>   | <i>Column 2<br/>Maximum strength</i> | <i>Column 3<br/>Route of administration, use or pharmaceutical form</i>                                  | <i>Column 4<br/>Treatment limitations</i> | <i>Column 5<br/>Maximum quantity</i>   |
|   |                                      | [ <sup>F232</sup> or in combination with Miconazole Nitrate, for athlete's foot and candidal intertrigo] |   |  |
|   |                                      | For use in adults and children not less than 10 years  |   |  |
|   |                                      | Cream, ointment or suppositories   |   |  |
| Hydrocortisone Butyrate   |                                      |  |   |  |
| Hydrocortisone Caprylate  |                                      |  |   |  |
| Hydrocortisone Hydrogen Succinate   |                                      |  |   |  |
| Hydrocortisone Sodium Phosphate   |                                      |  |   |  |
| Hydrocortisone Sodium Succinate   | Equivalent to 2.5mg Hydrocortisone   | External For aphthous ulceration of the mouth for adults and children not less than 12 years             |   | Container or package containing not more than equivalent to 50mg of Hydrocortisone |
|   |                                      | In the form of pellets   |   |  |

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|---|--------------------------------------|--|---|--|
| <i>Column 1<br/>Substance</i>   | <i>Column 2<br/>Maximum strength</i> | <i>Column 3<br/>Route of administration, use or pharmaceutical form</i>  | <i>Column 4<br/>Treatment limitations</i> | <i>Column 5<br/>Maximum quantity</i>   |
| [ <sup>196</sup> F]Hydrocyanic Acid]  |                                      |  |   |  |
| Hydroflumethiazide  |                                      |  |   |  |
| Hydroxychloroquine Sulphate   |                                      | Prophylaxis of malaria   |   |  |
| Hydroxyprogesterone   |                                      |  |   |  |
| Hydroxyprogesterone Enanthate   |                                      |  |   |  |
| Hydroxyprogesterone Hexanoate   |                                      |  |   |  |
| Hydroxyurea   |                                      |  |   |  |
| Hydroxyzine Embonate  |                                      |  |   |  |
| Hydroxyzine Hydrochloride   |                                      | (a) For the management of pruritis associated with acute or chronic urticaria or atopic dermatitis or contact dermatitis, in adults and in children not less than 12 years | (a) 25mg (MD)<br>75mg (MDD)               | (a) Container or package containing not more than 750mg of Hydroxyzine Hydrochloride |
|   |                                      | (b) For the management of pruritis associated with acute or chronic urticaria or atopic dermatitis or contact dermatitis,  | (b) 25 mg (MD)<br>50mg (MDD)              | (b) Container or package containing not more than 750mg of Hydroxyzine Hydrochloride |

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|---|--------------------------------------|---|---|--|
| <i>Column 1<br/>Substance</i>   | <i>Column 2<br/>Maximum strength</i> | <i>Column 3<br/>Route of administration, use or pharmaceutical form</i>             | <i>Column 4<br/>Treatment limitations</i> | <i>Column 5<br/>Maximum quantity</i>   |
|   |                                      | in children not less than 6 years but less than 12 years                            |   |  |
| Hyoscine  | (1) 0.15 per cent                    | (1) Internal<br><br>(2) External (except ophthalmic)                                |   |  |
| Hyoscine Butylbromide   |                                      | (1) Internal<br>(a) by inhaler<br>(b) otherwise than by inhaler                     | (b) 20mg (MD)<br>80mg (MDD)               | (b) Container or package containing not more than 240mg of Hyoscine Butylbromide |
| Hyoscine Hydrobromide   |                                      | (2) External<br>(1) Internal<br>(a) by inhaler<br>(b) otherwise than by inhaler     | (b) 300mcg (MD)<br>900mcg (MDD)           |  |
| Hyoscine Methobromide   |                                      | (2) External (except ophthalmic)<br>(1) Internal<br>(a) by inhaler<br>(b) otherwise | (b) 2.5mg (MD)<br>7.5mg (MDD)             |  |

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|---|--------------------------------------|---|--|--------------------------------------|
| <i>Column 1<br/>Substance</i>   | <i>Column 2<br/>Maximum strength</i> | <i>Column 3<br/>Route of administration, use or pharmaceutical form</i> | <i>Column 4<br/>Treatment limitations</i>  | <i>Column 5<br/>Maximum quantity</i> |
|   |                                      | than by inhaler   |  |                                      |
|   |                                      | (2) External  |  |                                      |
| Hyoscine Methonitrate   |                                      | (1) Internal  |  |                                      |
|   |                                      | (a) by inhaler  |  |                                      |
|   |                                      | (b) otherwise than by inhaler   | (b) 2.5mg (MD)<br>7.5mg (MDD)  |                                      |
|   |                                      | (2) External  |  |                                      |
| Hyoscyamine   |                                      | (1) Internal  |  |                                      |
|   |                                      | (a) by inhaler  |  |                                      |
|   |                                      | (b) otherwise than by inhaler   | (b) 300mcg (MD)<br>1mg (MDD)   |                                      |
|   |                                      | (2) External  |  |                                      |
| Hyoscyamine Hydrobromide  |                                      | (1) Internal  |  |                                      |
|   |                                      | (a) by inhaler  |  |                                      |
|   |                                      | (b) otherwise than by inhaler   | (b) Equivalent of 300mcg of Hyoscyamine (MD)<br>Equivalent of 1mg of Hyoscyamine (MDD) |                                      |
|   |                                      | (2) External  |  |                                      |
| Hyoscyamine Sulphate  |                                      | (1) Internal  |  |                                      |
|   |                                      | (a) by inhaler  |  |                                      |
|   |                                      | (b) otherwise than by inhaler   | (b) Equivalent of 300mcg of Hyoscyamine (MD)<br>Equivalent of 1mg of Hyoscyamine (MDD) |                                      |
|   |                                      | (2) External  |  |                                      |

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|---|--------------------------------------|---|--|--|
| <i>Column 1<br/>Substance</i>   | <i>Column 2<br/>Maximum strength</i> | <i>Column 3<br/>Route of administration, use or pharmaceutical form</i>   | <i>Column 4<br/>Treatment limitations</i>  | <i>Column 5<br/>Maximum quantity</i>   |
| Ibuprofen   |                                      | Rheumatic and muscular pain, pain of non-serious arthritic conditions, backache, neuralgia, migraine, headache, dental pain, dysmenorrhoea, feverishness, symptoms of colds and influenza | (1) Internal (1)(a) In the case of a prolonged release preparation 600mg (MD) 1,200mg (MDD) (b) in any other case 400mg (MD) 1,200mg (MDD) |  |
|   | (2) 5.0 per cent                     | (2) External  |  |  |
|   | [ <sup>F233</sup> (3) 10.0 per cent] | [ <sup>F233</sup> (3) External]   | [ <sup>F233</sup> (3) 125 mg (MD) 500 mg (MDD)]  | [ <sup>F233</sup> (3) Container or package containing not more than [ <sup>F234</sup> 50g] of medicinal product] |
| [ <sup>F196</sup> Ibuprofen Lysine  |                                      | Rheumatic and muscular pain, pain of non-serious arthritic  | (a) in the case of a prolonged release preparation 600 mg (MD) 1,200 mg (MDD)  |  |

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|---|--------------------------------------|--|--|--------------------------------------|
| <i>Column 1<br/>Substance</i>   | <i>Column 2<br/>Maximum strength</i> | <i>Column 3<br/>Route of administration, use or pharmaceutical form</i>  | <i>Column 4<br/>Treatment limitations</i>            | <i>Column 5<br/>Maximum quantity</i> |
|   |                                      | conditions, backache, neuralgia, migraine, headache, dental pain, dysmenorrhoea, feverishness, symptoms of colds and influenza |  |                                      |
|   |                                      | Internal   | (b) in any other case<br>400 mg (MD) 1,200 mg (MDD)] |                                      |
| Idarubicin Hydrochloride  |                                      |  |  |                                      |
| Idoxuridine   |                                      |  |  |                                      |
| Ifosfamide  |                                      |  |  |                                      |
| Ignatius Bean   |                                      |  |  |                                      |
| [ <sup>193</sup> F]Imidapril Hydrochloride]   |                                      |  |  |                                      |
| Imipenem Hydrochloride  |                                      |  |  |                                      |
| Imipramine  |                                      |  |  |                                      |
| Imipramine Hydrochloride  |                                      |  |  |                                      |
| Imipramine Ion Exchange Resin Bound Salt or Complex   |                                      |  |  |                                      |
| [ <sup>208</sup> F]Indapamide]  |                                      |  |  |                                      |
| Indapamide Hemihydrate  |                                      |  |  |                                      |
| Indomethacin  |                                      |  |  |                                      |

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|---|--|---|---|--|
| <i>Column 1<br/>Substance</i>   | <i>Column 2<br/>Maximum<br/>strength</i> | <i>Column 3<br/>Route of<br/>administration,<br/>use or<br/>pharmaceutical<br/>form</i> | <i>Column 4<br/>Treatment limitations</i> | <i>Column 5<br/>Maximum<br/>quantity</i> |
| Indomethacin  |  |   |   |  |
| Sodium  |  |   |   |  |
| Indoprofen  |  |   |   |  |
| Indoramin   |  |   |   |  |
| Hydrochloride   |  |   |   |  |
| Inosine   |  |   |   |  |
| Pranobex  |  |   |   |  |
| [ <sup>235</sup> F]Insulin]   |  |   |   |  |
| Iodamide  |  |   |   |  |
| Iodamide  |  |   |   |  |
| Meglumine   |  |   |   |  |
| Iodamide  |  |   |   |  |
| Sodium  |  |   |   |  |
| Iohexol   |  |   |   |  |
| Iomeprol  |  |   |   |  |
| Iopamidol   |  |   |   |  |
| Iopentol  |  |   |   |  |
| Iothalamic  |  |   |   |  |
| Acid  |  |   |   |  |
| Ioversol  |  |   |   |  |
| Ioxaglic  |  |   |   |  |
| Acid  |  |   |   |  |
| Ipratropium   |  |   |   |  |
| Bromide   |  |   |   |  |
| Iprindole   |  |   |   |  |
| Hydrochloride   |  |   |   |  |
| Iproniazid  |  |   |   |  |
| Phosphate   |  |   |   |  |
| [ <sup>197</sup> F]Irbesartan]  |  |   |   |  |
| Isoaminile  |  |   |   |  |
| Isoaminile  |  |   |   |  |
| Citrate   |  |   |   |  |
| Isocarboxazid   |  |   |   |  |

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| <i>Exemptions from the restrictions on the sale and supply of prescription only medicines</i> |  |  |   |  |
|---|--|--|---|--|
| <i>Column 1<br/>Substance</i>   | <i>Column 2<br/>Maximum<br/>strength</i> | <i>Column 3<br/>Route of<br/>administration,<br/>use or<br/>pharmaceutical<br/>form</i>            | <i>Column 4<br/>Treatment limitations</i>     | <i>Column 5<br/>Maximum<br/>quantity</i> |
| Isoconazole Nitrate   |  | External but in the case of vaginal use only external use for the treatment of vaginal candidiasis |   |  |
| Isoetharine   |  |  |   |  |
| Isoetharine Hydrochloride   |  |  |   |  |
| Isoetharine Mesylate  |  |  |   |  |
| Isoniazid   |  |  |   |  |
| Isoprenaline Hydrochloride  |  |  |   |  |
| Isoprenaline Sulphate   |  |  |   |  |
| Isopropamide Iodide   |  |  | Equivalent of 2.5mg of Isopropamide ion (MD)  |  |
|   |  |  | Equivalent of 5.0mg of Isopropamide ion (MDD) |  |
| Isotretinoin  |  |  |   |  |
| Isradipine  |  |  |   |  |
| Itraconazole  |  |  |   |  |
| Jaborandi   |  | External   |   |  |
| Kanamycin Acid Sulphate   |  |  |   |  |
| Kanamycin Sulphate  |  |  |   |  |
| Ketamine Hydrochloride  |  |  |   |  |



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|---|--------------------------------------|--|---|---|
| <i>Column 1<br/>Substance</i>   | <i>Column 2<br/>Maximum strength</i> | <i>Column 3<br/>Route of administration, use or pharmaceutical form</i>  | <i>Column 4<br/>Treatment limitations</i>             | <i>Column 5<br/>Maximum quantity</i>  |
| Ketoconazole  | 2.0 per cent                         | [ <sup>F236</sup> (a)] [ <sup>F237</sup> External] [ <sup>F236</sup> (a)]<br>For the prevention and treatment of dandruff and seborrhoeic dermatitis of the scalp<br>In the form of a shampoo<br>[ <sup>F238</sup> (b)]<br>For the treatment of the following mycotic infections of the skin: tinea pedis, tinea cruris and candidal intertrigo] | Maximum frequency of application of once every 3 days | [ <sup>F236</sup> (a)]<br>Container or package containing not more than 120ml of medicinal product and containing not more than 2,400mg of Ketoconazole |
| Ketoprofen  | 2.5 per cent                         | External<br>For rheumatic and muscular pain in adults and children not less than 12  | For maximum period of 7 days                          | Container or package containing not more than 30g of medicinal product  |
| Ketorolac   |                                      |  |   |   |
| Trometamol  |                                      |  |   |   |
| Ketotifen   |                                      |  |   |   |
| Fumarate  |                                      |  |   |   |
| Labetalol   |                                      |  |   |   |
| Hydrochloride   |                                      |  |   |   |

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| <i>Exemptions from the restrictions on the sale and supply of prescription only medicines</i> |   |   |   |  |
|---|---|---|---|--|
| <i>Column 1<br/>Substance</i>   | <i>Column 2<br/>Maximum strength</i>      | <i>Column 3<br/>Route of administration, use or pharmaceutical form</i>   | <i>Column 4<br/>Treatment limitations</i> | <i>Column 5<br/>Maximum quantity</i>   |
| Lachesine Chloride  |   |   |   |  |
| Lacidipine  |   |   |   |  |
| Lamotrigine   |   |   |   |  |
| Lanatoside C  |   |   |   |  |
| Lanatoside Complex A, B and C   |   |   |   |  |
| [ <sup>F208</sup> Lansoprazole]   |   |   |   |  |
| Latamoxef Disodium  |   |   |   |  |
| [ <sup>F208</sup> Lercanidipine Hydrochloride]  |   |   |   |  |
| Levallorphan Tartrate   |   |   |   |  |
| Levobunolol Hydrochloride   |   |   |   |  |
| [ <sup>F196</sup> Levocabastine Hydrochloride]  | Equivalent of 0.05 per cent Levocabastine | (1) Nasal sprays<br><br>For the symptomatic treatment of seasonal allergic rhinitis<br><br>(2) Aqueous eye drops<br><br>For the symptomatic treatment of seasonal allergic conjunctivitis |   | (1) Container or package containing not more than 10 ml of medicinal product<br><br>(2) Container or package containing not more than 4 ml of medicinal product] |
| [ <sup>F239</sup> Levocarnitine]  |   | [ <sup>F239</sup> For dietary supplementation]  |   |  |

| <i>Exemptions from the restrictions on the sale and supply of prescription only medicines</i> |                                      |  |  |                                      |
|---|--------------------------------------|--|--|--------------------------------------|
| <i>Column 1<br/>Substance</i>   | <i>Column 2<br/>Maximum strength</i> | <i>Column 3<br/>Route of administration, use or pharmaceutical form</i>                  | <i>Column 4<br/>Treatment limitations</i>                                | <i>Column 5<br/>Maximum quantity</i> |
| Levodopa  |                                      |  |  |                                      |
| [ <sup>F197</sup> Levofloxacin]   |                                      |  |  |                                      |
| Levonorgestrel  | [ <sup>F240</sup> 0.75mg]            | [ <sup>F240</sup> for use as an emergency contraceptive in women aged 16 years and over] |  |                                      |
| Lidoflazine   |                                      |  |  |                                      |
| Lignocaine  |                                      | Non-ophthalmic use   |  |                                      |
| Lignocaine Hydrochloride  |                                      | Non-ophthalmic use   |  |                                      |
| Lincomycin  |                                      |  |  |                                      |
| Lincomycin Hydrochloride  |                                      |  |  |                                      |
| Liothyronine Sodium   |                                      |  |  |                                      |
| Lisinopril  |                                      |  |  |                                      |
| Lithium Carbonate   |                                      |  | Equivalent of 5mg of Lithium (MD)<br>Equivalent of 15mg of Lithium (MDD) |                                      |
| Lithium Citrate   |                                      |  |  |                                      |
| Lithium Succinate   |                                      |  |  |                                      |
| Lithium Sulphate  |                                      |  | Equivalent of 5mg of Lithium (MD)<br>Equivalent of 15mg of Lithium (MDD) |                                      |
| Lobeline  |                                      | (1) Internal   | (1) 3mg (MD)   |                                      |

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|---|--|---|---|--------------------------------------|
| <i>Column 1<br/>Substance</i>   | <i>Column 2<br/>Maximum strength</i>                     | <i>Column 3<br/>Route of administration, use or pharmaceutical form</i>   | <i>Column 4<br/>Treatment limitations</i>                                     | <i>Column 5<br/>Maximum quantity</i> |
|   |  |   | 9mg (MDD)   |                                      |
|   |  | (2) External  |   |                                      |
| Lobeline Hydrochloride  |  | (1) Internal  | (1) Equivalent of 3mg of Lobeline (MD)<br>Equivalent of 9mg of Lobeline (MDD) |                                      |
|   |  | (2) External  |   |                                      |
| Lobeline Sulphate   |  | (1) Internal  | (1) Equivalent of 3mg of Lobeline (MD)<br>Equivalent of 9mg of Lobeline (MDD) |                                      |
|   |  | (2) External  |   |                                      |
| Lodoxamide Trometamol   | [ <sup>F241</sup> equivalent of 0.1 per cent Lodoxamide] | [ <sup>F242</sup> For the treatment of ocular signs and symptoms of allergic conjunctivitis, in adults and in children aged 4 years and over] |   |                                      |
| Lofepamine  |  |   |   |                                      |
| Lofepamine Hydrochloride  |  |   |   |                                      |
| Lofexidine Hydrochloride  |  |   |   |                                      |
| Lomefloxacin Hydrochloride  |  |   |   |                                      |
| Lomustine   |  |   |   |                                      |
| Loperamide Hydrochloride  |  | Treatment of acute diarrhoea  |   |                                      |
| Loratidine  |  |   | 10mg (MDD)  | <b>F243</b>                          |

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|---|--------------------------------------|---|---|--------------------------------------|
| <i>Column 1<br/>Substance</i>   | <i>Column 2<br/>Maximum strength</i> | <i>Column 3<br/>Route of administration,<br/>use or pharmaceutical form</i> | <i>Column 4<br/>Treatment limitations</i> | <i>Column 5<br/>Maximum quantity</i> |
| [ <sup>F209</sup> Lornoxicam]   |                                      |   |   |                                      |
| [ <sup>F209</sup> Losartan Potassium]   |                                      |   |   |                                      |
| Loxapine Succinate  |                                      |   |   |                                      |
| Lung Surfactant Porcine   |                                      |   |   |                                      |
| Luteinising Hormone   |                                      |   |   |                                      |
| Lymecycline   |                                      |   |   |                                      |
| Lynoestrenol  |                                      |   |   |                                      |
| Lypressin   |                                      |   |   |                                      |
| Lysuride Maleate  |                                      |   |   |                                      |
| Mafenide Acetate  |                                      |   |   |                                      |
| Mafenide Hydrochloride  |                                      |   |   |                                      |
| Mafenide Propionate   | 5.0 per cent                         | Eye drops   |   |                                      |
| Magnesium Fluoride  |                                      |   |   |                                      |
| Magnesium Metrizoate  |                                      |   |   |                                      |
| Mandragora Autumnalis   |                                      |   |   |                                      |
| Mannomustine Hydrochloride  |                                      |   |   |                                      |
| Maprotiline Hydrochloride   |                                      |   |   |                                      |
| Mebanazine  |                                      |   |   |                                      |

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| <i>Exemptions from the restrictions on the sale and supply of prescription only medicines</i> |                                      |   |  |  |
|---|--------------------------------------|---|--|--|
| <i>Column 1<br/>Substance</i>   | <i>Column 2<br/>Maximum strength</i> | <i>Column 3<br/>Route of administration, use or pharmaceutical form</i>   | <i>Column 4<br/>Treatment limitations</i>          | <i>Column 5<br/>Maximum quantity</i>                               |
| Mebendazole   |                                      | For oral use in the treatment of enterobiasis in adults and in children not less than 2 years   | 100mg (MD)   | Container or package containing not more than 800mg of Mebendazole |
| Mebeverine Hydrochloride  |                                      | [ <sup>F244</sup> (a) For the symptomatic relief of irritable bowel syndrome<br><br>(b) For uses other than the symptomatic relief of irritable bowel syndrome] | [ <sup>F244</sup> (a) 135 mg (MD)<br>405 mg (MDD)] |  |
| Mebeverine Pamoate  |                                      |   |  |  |
| Mebhydrolin   |                                      |   |  |  |
| Mebhydrolin Napadisylate  |                                      |   |  |  |
| Mecamylamine Hydrochloride  |                                      |   |  |  |
| Mecillinam  |                                      |   |  |  |
| Meclofenoxate Hydrochloride   |                                      |   |  |  |
| Medigoxin   |                                      |   |  |  |
| Medrogestone  |                                      |   |  |  |
| Medroxyprogesterone Acetate   |                                      |   |  |  |

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|---|--------------------------------------|---|---|--------------------------------------|
| <i>Column 1<br/>Substance</i>   | <i>Column 2<br/>Maximum strength</i> | <i>Column 3<br/>Route of administration, use or pharmaceutical form</i> | <i>Column 4<br/>Treatment limitations</i> | <i>Column 5<br/>Maximum quantity</i> |
| Mefenamic Acid  |                                      |   |   |                                      |
| Mefloquine Hydrochloride  |                                      |   |   |                                      |
| Mefruside   |                                      |   |   |                                      |
| Megestrol   |                                      |   |   |                                      |
| Megestrol Acetate   |                                      |   |   |                                      |
| Meglumine Gadopentetate   |                                      |   |   |                                      |
| Meglumine Iodoxamate  |                                      |   |   |                                      |
| Meglumine Ioglycamate   |                                      |   |   |                                      |
| Meglumine Iothalamate   |                                      |   |   |                                      |
| Meglumine Iotroxate   |                                      |   |   |                                      |
| Meglumine Ioxaglate   |                                      |   |   |                                      |
| [ <sup>F208</sup> Meloxicam]  |                                      |   |   |                                      |
| Melphalan   |                                      |   |   |                                      |
| Melphalan Hydrochloride   |                                      |   |   |                                      |
| Menotrophin   |                                      |   |   |                                      |
| Mepenzolate Bromide   |                                      |   | 25mg (MD)<br>75mg (MDD)                   |                                      |
| Mephesisin  |                                      |   |   |                                      |
| Mephesisin Carbamate  |                                      |   |   |                                      |
| Mepivacaine Hydrochloride   |                                      | Any use except ophthalmic use   |   |                                      |

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|---|--|---|---|--|
| <i>Column 1<br/>Substance</i>   | <i>Column 2<br/>Maximum<br/>strength</i> | <i>Column 3<br/>Route of<br/>administration,<br/>use or<br/>pharmaceutical<br/>form</i> | <i>Column 4<br/>Treatment limitations</i> | <i>Column 5<br/>Maximum<br/>quantity</i> |
| Meptazinol<br>Hydrochloride   |  |   |   |  |
| Mequitazine   |  |   |   |  |
| [ <sup>197</sup> F]Mercaptamine<br>Bitartrate]  |  |   |   |  |
| Mercaptopurine  |  |   |   |  |
| Mersalyl  |  |   |   |  |
| Mersalyl<br>Acid  |  |   |   |  |
| Mesalazine  |  |   |   |  |
| Mesna   |  |   |   |  |
| Mestranol   |  |   |   |  |
| Metaraminol<br>Tartrate   |  |   |   |  |
| Metergoline   |  |   |   |  |
| Metformin<br>Hydrochloride  |  |   |   |  |
| Methacycline  |  |   |   |  |
| Methacycline<br>Calcium   |  |   |   |  |
| Methacycline<br>Hydrochloride   |  |   |   |  |
| Methallenoestril  |  |   |   |  |
| Methicillin<br>Sodium   |  |   |   |  |
| Methixene   |  |   |   |  |
| Methixene<br>Hydrochloride  |  |   |   |  |
| Methocarbamol   |  |   |   |  |
| Methocidin  |  | Throat<br>lozenges<br>and throat<br>pastilles   |   |  |



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|---|--|---|---|--|
| <i>Column 1<br/>Substance</i>   | <i>Column 2<br/>Maximum<br/>strength</i> | <i>Column 3<br/>Route of<br/>administration,<br/>use or<br/>pharmaceutical<br/>form</i>   | <i>Column 4<br/>Treatment limitations</i> | <i>Column 5<br/>Maximum<br/>quantity</i> |
| Methohexitone<br>Sodium   |  |   |   |  |
| Methoin   |  |   |   |  |
| Methoserpidine  |  |   |   |  |
| Methotrexate  |  |   |   |  |
| Methotrexate<br>Sodium  |  |   |   |  |
| Methotrimeprazine   |  |   |   |  |
| Methotrimeprazine<br>Hydrochloride  |  |   |   |  |
| Methotrimeprazine<br>Maleate  |  |   |   |  |
| Methoxamine 0.25 per<br>Hydrochloride cent  |  | Nasal sprays<br>or nasal<br>drops not<br>containing<br>liquid<br>paraffin as a<br>vehicle |   |  |
| Methsuximide  |  |   |   |  |
| Methyclothiazide  |  |   |   |  |
| Methyldopa  |  |   |   |  |
| Methyldopate<br>Hydrochloride   |  |   |   |  |
| Methylephedrine<br>Hydrochloride  |  |   | 30mg (MD)<br>60mg (MDD)                   |  |
| Methylprednisolone  |  |   |   |  |
| Methylprednisolone<br>Acetate   |  |   |   |  |
| Methylprednisolone<br>Sodium<br>Succinate   |  |   |   |  |
| Methylthiouracil  |  |   |   |  |
| Methysergide<br>Maleate   |  |   |   |  |

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|---|--|--|---|--|
| <i>Column 1<br/>Substance</i>   | <i>Column 2<br/>Maximum<br/>strength</i> | <i>Column 3<br/>Route of<br/>administration,<br/>use or<br/>pharmaceutical<br/>form</i>                                    | <i>Column 4<br/>Treatment limitations</i> | <i>Column 5<br/>Maximum<br/>quantity</i> |
| Metipranolol  |  |  |   |  |
| Metirosine  |  |  |   |  |
| Metoclopramide<br>Hydrochloride   |  |  |   |  |
| Metolazone  |  |  |   |  |
| Metoprolol<br>Fumarate  |  |  |   |  |
| Metoprolol<br>Succinate   |  |  |   |  |
| Metoprolol<br>Tartrate  |  |  |   |  |
| Metronidazole   |  |  |   |  |
| Metronidazole<br>Benzoate   |  |  |   |  |
| Metyrapone  |  |  |   |  |
| Mexiletine<br>Hydrochloride   |  |  |   |  |
| Mezlocillin<br>Sodium   |  |  |   |  |
| Mianserin<br>Hydrochloride  |  |  |   |  |
| Miconazole  |  | External but<br>in the case<br>of vaginal<br>use only<br>external<br>use for the<br>treatment<br>of vaginal<br>candidiasis |   |  |
| Miconazole<br>Nitrate   |  | External but<br>in the case<br>of vaginal<br>use only<br>external<br>use for the<br>treatment                              |   |  |

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|---|--|---|---|--------------------------------------|
| <i>Column 1<br/>Substance</i>   | <i>Column 2<br/>Maximum strength</i>   | <i>Column 3<br/>Route of administration, use or pharmaceutical form</i>   | <i>Column 4<br/>Treatment limitations</i> | <i>Column 5<br/>Maximum quantity</i> |
|   |  | of vaginal candidiasis  |   |                                      |
| Mifepristone  |  |   |   |                                      |
| Miglitol  |  |   |   |                                      |
| Milrinone   |  |   |   |                                      |
| Milrinone Lactate   |  |   |   |                                      |
| Minocycline   |  |   |   |                                      |
| Minocycline Hydrochloride   |  |   |   |                                      |
| Minoxidil   | [ <sup>F245</sup> (1) 2.0 per cent]<br><br>[ <sup>F245</sup> (2) 5.0 per cent] | [ <sup>F245</sup> (1) External<br><br>(2) External use for the treatment of alopecia androgenetica, in men aged 18 to 65 (but not in women);] |   |                                      |
| [ <sup>F193</sup> Mirtazapine]  |  |   |   |                                      |
| Misoprostol   |  |   |   |                                      |
| Mitobronitol  |  |   |   |                                      |
| Mitomycin   |  |   |   |                                      |
| Mitozantrone Hydrochloride  |  |   |   |                                      |
| Mivacurium Chloride   |  |   |   |                                      |
| [ <sup>F218</sup> Mizolastine]  |  |   |   |                                      |
| Moclobemide   |  |   |   |                                      |
| [ <sup>F197</sup> Modafinil]  |  |   |   |                                      |
| [ <sup>F194</sup> Moexipril Hydrochloride]  |  |   |   |                                      |

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|---|-------------------------|--|------------------------------|-------------------------|
| <i>Column 1</i>   | <i>Column 2</i>         | <i>Column 3</i>  | <i>Column 4</i>              | <i>Column 5</i>         |
| <i>Substance</i>  | <i>Maximum strength</i> | <i>Route of administration, use or pharmaceutical form</i> | <i>Treatment limitations</i> | <i>Maximum quantity</i> |
| Molgramostim  |                         |  |                              |                         |
| Molindone Hydrochloride   |                         |  |                              |                         |
| Mometasone Furoate  |                         |  |                              |                         |
| Moracizine Hydrochloride  |                         |  |                              |                         |
| Morazone Hydrochloride  |                         |  |                              |                         |
| [ <sup>193</sup> F]Moxonidine]  |                         |  |                              |                         |
| Mupirocin   |                         |  |                              |                         |
| Mupirocin Calcium   |                         |  |                              |                         |
| Mustine Hydrochloride   |                         |  |                              |                         |
| Nabilone  |                         |  |                              |                         |
| Nabumetone  |                         |  |                              |                         |
| Nadolol   |                         |  |                              |                         |
| Nafarelin Acetate   |                         |  |                              |                         |
| Naftidrofuryl Oxalate   |                         |  |                              |                         |
| Naftifine Hydrochloride   |                         |  |                              |                         |
| Nalbuphine Hydrochloride  |                         |  |                              |                         |
| Nalidixic Acid  |                         |  |                              |                         |
| Nalorphine Hydrobromide   |                         |  |                              |                         |
| Naloxone Hydrochloride  |                         |  |                              |                         |
| Naltrexone Hydrochloride  |                         |  |                              |                         |

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| <i>Exemptions from the restrictions on the sale and supply of prescription only medicines</i> |                                      |   |   |  |
|---|--------------------------------------|---|---|--|
| <i>Column 1<br/>Substance</i>   | <i>Column 2<br/>Maximum strength</i> | <i>Column 3<br/>Route of administration, use or pharmaceutical form</i>                                       | <i>Column 4<br/>Treatment limitations</i> | <i>Column 5<br/>Maximum quantity</i>   |
| Naphazoline Hydrochloride   | (1) 0.05 per cent                    | (1) Nasal sprays or nasal drops not containing liquid paraffin as a vehicle                                   |   |  |
|   | (2) 0.015 per cent                   | (2) Eye drops   |   |  |
| Naphazoline Nitrate   | 0.05 per cent                        | Nasal sprays or nasal drops not containing liquid paraffin as a vehicle                                       |   |  |
| Naproxen  |                                      |   |   |  |
| Naproxen Sodium   |                                      |   |   |  |
| [ <sup>F197</sup> Naratriptan Hydrochloride]  |                                      |   |   |  |
| Natamycin   |                                      |   |   |  |
| [ <sup>F209</sup> Nebivolol Hydrochloride]  |                                      |   |   |  |
| Nedocromil Sodium   | [ <sup>F246</sup> 2.0 per cent]      | [ <sup>F246</sup> For the prevention, relief and treatment of seasonal and perennial allergic conjunctivitis] |   | [ <sup>F246</sup> Container or package containing not more than 3 ml of medicinal product] |
| Nefazodone Hydrochloride  |                                      |   |   |  |
| Nefopam Hydrochloride   |                                      |   |   |  |
| Neomycin  |                                      |   |   |  |

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| <i>Exemptions from the restrictions on the sale and supply of prescription only medicines</i> |  |   |   |  |
|---|--|---|---|--|
| <i>Column 1<br/>Substance</i>   | <i>Column 2<br/>Maximum<br/>strength</i> | <i>Column 3<br/>Route of<br/>administration,<br/>use or<br/>pharmaceutical<br/>form</i> | <i>Column 4<br/>Treatment limitations</i> | <i>Column 5<br/>Maximum<br/>quantity</i> |
| Neomycin<br>Oleate  |  |   |   |  |
| Neomycin<br>Palmitate   |  |   |   |  |
| Neomycin<br>Sulphate  |  |   |   |  |
| Neomycin<br>Undecanoate   |  |   |   |  |
| Neostigmine<br>Bromide  |  |   |   |  |
| Neostigmine<br>Methylsulphate   |  |   |   |  |
| Netilmicin<br>Sulphate  |  |   |   |  |
| Nicardipine<br>Hydrochloride  |  |   |   |  |
| Nicergoline   |  |   |   |  |
| [ <sup>F218</sup> Niceritrol]   |  |   |   |  |
| Nicotinic<br>Acid   |  | Any use,<br>except<br>for the<br>treatment of<br>hyperlipidaemia                        | 600mg (MDD)                               |  |
| Nicoumalone   |  |   |   |  |
| Nifedipine  |  |   |   |  |
| Nifenazone  |  |   |   |  |
| Nikethamide   |  |   |   |  |
| [ <sup>F196</sup> Nilutamide]   |  |   |   |  |
| Nimodipine  |  |   |   |  |
| Niridazole  |  |   |   |  |
| [ <sup>F209</sup> Nisoldipine]  |  |   |   |  |
| Nitrendipine  |  |   |   |  |
| Nitrofurantoin  |  |   |   |  |

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|---|--|---|---|--|
| <i>Column 1<br/>Substance</i>   | <i>Column 2<br/>Maximum<br/>strength</i> | <i>Column 3<br/>Route of<br/>administration,<br/>use or<br/>pharmaceutical<br/>form</i>                               | <i>Column 4<br/>Treatment limitations</i>                                 | <i>Column 5<br/>Maximum<br/>quantity</i> |
| Nitrofurazone   |  |   |   |  |
| Nizatidine  |  | For the prevention [F247 and treatment] of the symptoms of food-related heartburn [F247 and meal-induced indigestion] | 75mg (MD)<br>[F248 150mg (MDD)]<br>[F249 For a maximum period of 14 days] |  |
| Nomifensine Maleate   |  |   |   |  |
| Noradrenaline   |  |   |   |  |
| Noradrenaline Acid Tartrate   |  |   |   |  |
| Norethisterone  |  |   |   |  |
| Norethisterone Acetate  |  |   |   |  |
| Norethisterone Enanthate  |  |   |   |  |
| Norethynodrel   |  |   |   |  |
| Norfloxacin   |  |   |   |  |
| Norgestimate  |  |   |   |  |
| Norgestrel  |  |   |   |  |
| Nortriptyline Hydrochloride   |  |   |   |  |
| Noscapine   |  |   |   |  |

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|---|--------------------------------------|--|---|---|
| <i>Column 1<br/>Substance</i>   | <i>Column 2<br/>Maximum strength</i> | <i>Column 3<br/>Route of administration, use or pharmaceutical form</i>  | <i>Column 4<br/>Treatment limitations</i> | <i>Column 5<br/>Maximum quantity</i>  |
| Noscapine Hydrochloride   |                                      |  |   |   |
| Novobiocin Calcium  |                                      |  |   |   |
| Novobiocin Sodium   |                                      |  |   |   |
| Nux Vomica Seed   |                                      |  |   |   |
| Nystatin  | [ <sup>F250</sup> 3.0 per cent]      | [ <sup>F250</sup> External<br>For use in combination with Hydrocortisone of maximum strength 0.5 per cent for intertrigo<br><br>For use in adults and children not less than 10 years] |   | [ <sup>F250</sup> Container or package containing not more than 15g of medicinal product] |
| Octacosactrin   |                                      |  |   |   |
| Octreotide  |                                      |  |   |   |
| Oestradiol  |                                      |  |   |   |
| Oestradiol Benzoate   |                                      |  |   |   |
| Oestradiol Cypionate  |                                      |  |   |   |
| Oestradiol Dipropionate   |                                      |  |   |   |
| Oestradiol Diundecanoate  |                                      |  |   |   |
| Oestradiol Enanthate  |                                      |  |   |   |



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|---|--|---|---|--|
| <i>Column 1<br/>Substance</i>   | <i>Column 2<br/>Maximum<br/>strength</i> | <i>Column 3<br/>Route of<br/>administration,<br/>use or<br/>pharmaceutical<br/>form</i> | <i>Column 4<br/>Treatment limitations</i> | <i>Column 5<br/>Maximum<br/>quantity</i> |
| Oestradiol<br>Phenylpropionate  |  |   |   |  |
| Oestradiol<br>Undecanoate   |  |   |   |  |
| Oestradiol<br>Valerate  |  |   |   |  |
| Oestriol  |  |   |   |  |
| Oestriol<br>Succinate   |  |   |   |  |
| Oestrogenic<br>Substances<br>Conjugated   |  |   |   |  |
| Oestrone  |  |   |   |  |
| Ofloxacin   |  |   |   |  |
| Olsalazine<br>Sodium  |  |   |   |  |
| Omeprazole  |  |   |   |  |
| [ <sup>193</sup> F]Omeprazole<br>Magnesium]   |  |   |   |  |
| Ondansetron<br>Hydrochloride  |  |   |   |  |
| Orciprenaline<br>Sulphate   |  |   |   |  |
| Orphenadrine<br>Citrate   |  |   |   |  |
| Orphenadrine<br>Hydrochloride   |  |   |   |  |
| Ouabain   |  |   |   |  |
| Ovarian<br>Gland Dried  |  |   |   |  |
| Oxamniquine   |  |   |   |  |
| Oxantel<br>Embonate   |  |   |   |  |
| Oxaprozin   |  |   |   |  |

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|---|--------------------------------------|---|---|--|
| <i>Column 1<br/>Substance</i>   | <i>Column 2<br/>Maximum strength</i> | <i>Column 3<br/>Route of administration, use or pharmaceutical form</i> | <i>Column 4<br/>Treatment limitations</i> | <i>Column 5<br/>Maximum quantity</i>                               |
| Oxatomide   |                                      |   |   |  |
| Oxedrine Tartrate   |                                      |   |   |  |
| Oxethazaine   |                                      |   | 10mg (MD)<br>30mg (MDD)                   | Container or package containing not more than 400mg of Oxethazaine |
| Oxitropium Bromide  |                                      |   |   |  |
| Oxolinic Acid   |                                      |   |   |  |
| Oxpentifylline  |                                      |   |   |  |
| Oxprenolol Hydrochloride  |                                      |   |   |  |
| Oxybuprocaine Hydrochloride   |                                      | Non-ophthalmic use  |   |  |
| Oxybutynin Hydrochloride  |                                      |   |   |  |
| Oxypertine  |                                      |   |   |  |
| Oxypertine Hydrochloride  |                                      |   |   |  |
| Oxyphenbutazone   |                                      |   |   |  |
| Oxyphencylimine Hydrochloride   |                                      |   |   |  |
| Oxyphenonium Bromide  |                                      |   | 5mg (MD)<br>15mg (MDD)                    |  |
| Oxytetracycline   |                                      |   |   |  |
| Oxytetracycline Calcium   |                                      |   |   |  |
| Oxytetracycline Dihydrate   |                                      |   |   |  |

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|---|---|---|--|--------------------------------------|
| <i>Column 1<br/>Substance</i>   | <i>Column 2<br/>Maximum strength</i>                          | <i>Column 3<br/>Route of administration, use or pharmaceutical form</i> | <i>Column 4<br/>Treatment limitations</i>  | <i>Column 5<br/>Maximum quantity</i> |
| Oxytetracycline Hydrochloride   |   |   |  |                                      |
| Oxytocin, natural   |   |   |  |                                      |
| Oxytocin, synthetic   |   |   |  |                                      |
| Pancreatin  | (1) 21,000 European Pharmacopoeia units of lipase per capsule | (1) capsules  |  |                                      |
|   | (2) 25,000 European Pharmacopoeia units of lipase per gram    | (2) powder  |  |                                      |
| Pancuronium Bromide   |   |   |  |                                      |
| [ <sup>208</sup> F]Pantoprazole Sodium]   |   |   |  |                                      |
| Papaverine  |   | (1) By inhaler  |  |                                      |
|   |   | (2) Otherwise than by inhaler   | (2) 50mg (MD)<br>150mg (MDD)   |                                      |
| Papaverine Hydrochloride  |   | (1) By inhaler  |  |                                      |
|   |   | (2) Otherwise than by inhaler   | (2) Equivalent of 50mg of Papaverine (MD)<br>Equivalent of 150mg of Papaverine (MDD) |                                      |
| [ <sup>198</sup> F]Paracetamol (1) [ <sup>251</sup> F]250mg]                                  |   | (1) Non-effervescent tablets and capsules                               |  | (1) The quantity sold or supplied in |

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|---|--------------------------------------|---|---|--|
| <i>Column 1<br/>Substance</i>   | <i>Column 2<br/>Maximum strength</i> | <i>Column 3<br/>Route of administration, use or pharmaceutical form</i>   | <i>Column 4<br/>Treatment limitations</i> | <i>Column 5<br/>Maximum quantity</i>   |
|   |                                      | [ <sup>F252</sup> wholly or mainly] for use in children aged less than 12 years   |   | one container or package shall not exceed 32<br>The quantity of _____ of non-effervescent tablets, capsules or a combination of both sold or supplied to a person at any one time shall not exceed 100 |
|   | (2) 500 mg                           | (2) Non-effervescent tablets and capsules [ <sup>F253</sup> wholly or mainly] for use in adults and children not less than 12 years |   | (2) The quantity sold or supplied in one container or package shall not exceed 32<br>The quantity of non-effervescent tablets, capsules or a   |
|   |                                      | (3) All preparations other than non-effervescent tablets and capsules   |   |  |

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|---|--------------------------------------|---|---|--|
| <i>Column 1<br/>Substance</i>   | <i>Column 2<br/>Maximum strength</i> | <i>Column 3<br/>Route of administration, use or pharmaceutical form</i> | <i>Column 4<br/>Treatment limitations</i> | <i>Column 5<br/>Maximum quantity</i>   |
|   |                                      |   |   | combination of both sold or supplied to a person at any one time shall not exceed 100] |
| Paraldehyde   |                                      |   |   |  |
| Paramethadione  |                                      |   |   |  |
| Paramethasone Acetate   |                                      |   |   |  |
| Parathyroid Gland   |                                      |   |   |  |
| Pargyline Hydrochloride   |                                      |   |   |  |
| Paroxetine Hydrochloride  |                                      |   |   |  |
| Pecilocin   |                                      |   |   |  |
| Penamcillin   |                                      |   |   |  |
| Penbutolol Sulphate   |                                      |   |   |  |
| [ <sup>32</sup> P] Penciclovir  |                                      |   |   |  |
| Penicillamine   |                                      |   |   |  |
| Penicillamine Hydrochloride   |                                      |   |   |  |
| Pentamidine Isethionate   |                                      |   |   |  |
| Penthienate Bromide   |                                      |   | 5mg (MD)<br>15mg (MDD)                    |  |

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|---|--|---|---|--|
| <i>Column 1<br/>Substance</i>   | <i>Column 2<br/>Maximum<br/>strength</i> | <i>Column 3<br/>Route of<br/>administration,<br/>use or<br/>pharmaceutical<br/>form</i> | <i>Column 4<br/>Treatment limitations</i> | <i>Column 5<br/>Maximum<br/>quantity</i> |
| Pentolinium<br>Tartrate   |  |   |   |  |
| Perfluamine   |  |   |   |  |
| Pergolide<br>Mesylate   |  |   |   |  |
| Perhexiline<br>Maleate  |  |   |   |  |
| Pericyazine   |  |   |   |  |
| Perindopril   |  |   |   |  |
| Perindopril<br>Erbumine   |  |   |   |  |
| Perphenazine  |  |   |   |  |
| Phenacetin  | 0.1 per cent                             |   |   |  |
| Phenazone   |  | External  |   |  |
| Phenazone<br>Salicylate   |  |   |   |  |
| Phenbutrazate<br>Hydrochloride  |  |   |   |  |
| Phenelzine<br>Sulphate  |  |   |   |  |
| Phenethicillin<br>Potassium   |  |   |   |  |
| Phenformin<br>Hydrochloride   |  |   |   |  |
| Phenglutarimide<br>Hydrochloride  |  |   |   |  |
| Phenindione   |  |   |   |  |
| [ <sup>254</sup> F-Phenolphthalein.]  |  |   |   |  |
| Phenoxybenzamine<br>Hydrochloride   |  |   |   |  |
| Phenoxyethylpenicillin  |  |   |   |  |
| Phenoxyethylpenicillin<br>Calcium   |  |   |   |  |

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|---|--|--|--|--|
| <i>Column 1<br/>Substance</i>   | <i>Column 2<br/>Maximum<br/>strength</i> | <i>Column 3<br/>Route of<br/>administration,<br/>use or<br/>pharmaceutical<br/>form</i>  | <i>Column 4<br/>Treatment limitations</i>                        | <i>Column 5<br/>Maximum<br/>quantity</i> |
| Phenoxymethylpenicillin<br>Potassium  |  |  |  |  |
| Phenprocoumon   |  |  |  |  |
| Phensuximide  |  |  |  |  |
| Phentolamine<br>Hydrochloride   |  |  |  |  |
| Phentolamine<br>Mesylate  |  |  |  |  |
| Phenylbutazone  |  |  |  |  |
| Phenylbutazone<br>Sodium  |  |  |  |  |
| Phenylpropanolamine<br>Hydrochloride  |  | Internal<br>(1) all<br>preparations<br>except<br>prolonged<br>release<br>capsules,<br>nasal sprays<br>and nasal<br>drops<br><br>(2)<br>prolonged<br>release<br>capsules<br><br>(3) 2.0 per<br>cent | (1) 25mg (MD)<br>100mg (MDD)<br><br>(2) 50mg (MD)<br>100mg (MDD) |  |
| Phenytoin   |  |  |  |  |
| Phenytoin<br>Sodium   |  |  |  |  |
| Phthalylsulphathiazole  |  |  |  |  |
| Physostigmine   |  |  |  |  |
| Physostigmine<br>Aminoxide<br>Salicylate  |  |  |  |  |

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|---|--|---|---|--|
| <i>Column 1<br/>Substance</i>   | <i>Column 2<br/>Maximum<br/>strength</i> | <i>Column 3<br/>Route of<br/>administration,<br/>use or<br/>pharmaceutical<br/>form</i> | <i>Column 4<br/>Treatment limitations</i> | <i>Column 5<br/>Maximum<br/>quantity</i> |
| Physostigmine<br>Salicylate   |  |   |   |  |
| Physostigmine<br>Sulphate   |  |   |   |  |
| [ <sup>196</sup> F]Phytomenadione   |  | Any use<br>except the<br>prevention<br>or<br>treatment of<br>haemorrhagic<br>disorders] |   |  |
| Picrotoxin  |  |   |   |  |
| Pilocarpine   |  |   |   |  |
| Pilocarpine<br>Hydrochloride  |  |   |   |  |
| Pilocarpine<br>Nitrate  |  |   |   |  |
| Pimozide  |  |   |   |  |
| Pindolol  |  |   |   |  |
| Pipenzolate<br>Bromide  |  |   | 5mg (MD)<br>15mg (MDD)                    |  |
| Piperacillin<br>Sodium  |  |   |   |  |
| Piperazine<br>Oestrone<br>Sulphate  |  |   |   |  |
| Piperidolate<br>Hydrochloride   |  |   | 50mg (MD)<br>150mg (MDD)                  |  |
| Pipothiazine<br>Palmitate   |  |   |   |  |
| Piracetam   |  |   |   |  |
| Pirbuterol<br>Acetate   |  |   |   |  |
| Pirbuterol<br>Hydrochloride   |  |   |   |  |



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|--|--------------------------------------|--|---|--|
| <i>Column 1<br/>Substance</i>  | <i>Column 2<br/>Maximum strength</i> | <i>Column 3<br/>Route of administration, use or pharmaceutical form</i>  | <i>Column 4<br/>Treatment limitations</i> | <i>Column 5<br/>Maximum quantity</i>                                   |
| [ <sup>F255</sup> Pirenzepine Dihydrochloride Monohydrate]<br>Pirenzepine Hydrochloride<br>Piretanide                  |                                      |  |   |  |
| Piroxicam  | 0.5 per cent                         | External<br><br>For the relief of rheumatic pain, pain of non-serious arthritic conditions and muscular aches, pains and swellings such as strains, sprains and sports injuries<br><br>For use in adults and children not less than 12 years | For maximum period of 7 days              | Container or package containing not more than 30g of medicinal product |
| [ <sup>F218</sup> Piroxicam Beta-cyclodextrin]<br>Pituitary Gland (Whole Dried)<br>Pituitary Powdered (Posterior Lobe) |                                      | By inhaler<br><br>By inhaler   |   |  |

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|---|--|---|---|--|
| <i>Column 1<br/>Substance</i>   | <i>Column 2<br/>Maximum<br/>strength</i> | <i>Column 3<br/>Route of<br/>administration,<br/>use or<br/>pharmaceutical<br/>form</i> | <i>Column 4<br/>Treatment limitations</i> | <i>Column 5<br/>Maximum<br/>quantity</i> |
| Pivampicillin   |  |   |   |  |
| Pivampicillin<br>Hydrochloride  |  |   |   |  |
| Pivmecillinam   |  |   |   |  |
| Pivmecillinam<br>Hydrochloride  |  |   |   |  |
| Pizotifen   |  |   |   |  |
| Pizotifen<br>Malate   |  |   |   |  |
| Plicamycin  |  |   |   |  |
| Podophyllotoxin   |  |   |   |  |
| Podophyllum   |  |   |   |  |
| Podophyllum<br>Indian   |  |   |   |  |
| Podophyllum<br>Resin  | 20.0 per<br>cent                         | External<br><br>Ointment or<br>impregnated<br>plaster                                   |   |  |
| Poldine<br>Methylsulphate   |  |   | 2mg (MD)<br>6mg (MDD)                     |  |
| Polidexide  |  |   |   |  |
| Polyestradiol<br>Phosphate  |  |   |   |  |
| Polymyxin<br>B Sulphate   |  |   |   |  |
| Polythiazide  |  |   |   |  |
| Poppy<br>Capsule  |  |   |   |  |
| Potassium<br>Arsenite   | 0.0127 per<br>cent                       |   |   |  |
| Potassium<br>Bromide  |  |   |   |  |
| Potassium<br>Canrenoate   |  |   |   |  |

| <i>Exemptions from the restrictions on the sale and supply of prescription only medicines</i> |                                      |   |   |                                      |
|---|--------------------------------------|---|---|--------------------------------------|
| <i>Column 1<br/>Substance</i>   | <i>Column 2<br/>Maximum strength</i> | <i>Column 3<br/>Route of administration, use or pharmaceutical form</i> | <i>Column 4<br/>Treatment limitations</i> | <i>Column 5<br/>Maximum quantity</i> |
| Potassium Clavulanate   |                                      |   |   |                                      |
| Potassium Perchlorate   |                                      |   |   |                                      |
| Practolol   |                                      |   |   |                                      |
| Pralidoxime Chloride  |                                      |   |   |                                      |
| Pralidoxime Iodide  |                                      |   |   |                                      |
| Pralidoxime Mesylate  |                                      |   |   |                                      |
| [ <sup>197</sup> F]Pramipexole Hydrochloride]   |                                      |   |   |                                      |
| Pravastatin Sodium  |                                      |   |   |                                      |
| Prazosin Hydrochloride  |                                      |   |   |                                      |
| Prednisolone  |                                      |   |   |                                      |
| Prednisolone Acetate  |                                      |   |   |                                      |
| Prednisolone Butylacetate   |                                      |   |   |                                      |
| Prednisolone Hexanoate  |                                      |   |   |                                      |
| Prednisolone Metasulphobenzoate   |                                      |   |   |                                      |
| Prednisolone Metasulphobenzoate Sodium  |                                      |   |   |                                      |
| Prednisolone Pivalate   |                                      |   |   |                                      |
| Prednisolone Sodium Phosphate   |                                      |   |   |                                      |

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| <i>Exemptions from the restrictions on the sale and supply of prescription only medicines</i> |                                      |   |   |  |
|---|--------------------------------------|---|---|--|
| <i>Column 1<br/>Substance</i>   | <i>Column 2<br/>Maximum strength</i> | <i>Column 3<br/>Route of administration, use or pharmaceutical form</i>   | <i>Column 4<br/>Treatment limitations</i> | <i>Column 5<br/>Maximum quantity</i>                                       |
| Prednisolone  |                                      |   |   |  |
| Steaglate   |                                      |   |   |  |
| Prednisone  |                                      |   |   |  |
| Prednisone Acetate  |                                      |   |   |  |
| Prenalterol Hydrochloride   |                                      |   |   |  |
| Prenylamine Lactate   |                                      |   |   |  |
| Prilocaine Hydrochloride  |                                      | Non-ophthalmic use  |   |  |
| Primidone   |                                      |   |   |  |
| Probenecid  |                                      |   |   |  |
| Probutol  |                                      |   |   |  |
| Procainamide Hydrochloride  |                                      |   |   |  |
| Procaine Hydrochloride  |                                      | Non-ophthalmic use  |   |  |
| Procaine Penicillin   |                                      |   |   |  |
| Procarbazine Hydrochloride  |                                      |   |   |  |
| Prochlorperazine  |                                      |   |   |  |
| Prochlorperazine Edisylate  |                                      |   |   |  |
| Prochlorperazine Maleate  | [ <sup>F212</sup> 3mg]               | [ <sup>F212</sup> Buccal tablets for the treatment of nausea and vomiting in cases of previously diagnosed migraine | [ <sup>F212</sup> 12mg (MDD)]             | [ <sup>F212</sup> Container or package containing not more than 8 tablets] |

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| <i>Column 1<br/>Substance</i>   | <i>Column 2<br/>Maximum<br/>strength</i> | <i>Column 3<br/>Route of<br/>administration,<br/>use or<br/>pharmaceutical<br/>form</i> | <i>Column 4<br/>Treatment limitations</i> | <i>Column 5<br/>Maximum<br/>quantity</i> |
|   |  | only. For use in persons aged 18 years and over.]                                       |   |  |
| Prochlorperazine Mesylate   |  |   |   |  |
| Procyclidine Hydrochloride  |  |   |   |  |
| Progesterone  |  |   |   |  |
| Prolactin   |  |   |   |  |
| Proligestone  |  |   |   |  |
| Prolintane Hydrochloride  |  |   |   |  |
| Promazine Embonate  |  |   |   |  |
| Promazine Hydrochloride   |  |   |   |  |
| Propafenone   |  |   |   |  |
| Propafenone Hydrochloride   |  |   |   |  |
| Propanidid  |  |   |   |  |
| Propantheline Bromide   |  |   | 15mg (MD)<br>45mg (MDD)                   |  |
| [ <sup>F209</sup> Propiverine Hydrochloride]  |  |   |   |  |
| Propofol  |  |   |   |  |
| Propranolol Hydrochloride   |  |   |   |  |
| Propylthiouracil  |  |   |   |  |
| Proquazone  |  |   |   |  |
| Protamine Sulphate  |  |   |   |  |

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| <i>Column 1<br/>Substance</i>   | <i>Column 2<br/>Maximum<br/>strength</i> | <i>Column 3<br/>Route of<br/>administration,<br/>use or<br/>pharmaceutical<br/>form</i>   | <i>Column 4<br/>Treatment limitations</i>  | <i>Column 5<br/>Maximum<br/>quantity</i>   |
| Prothionamide   |  |   |  |  |
| Protirelin  |  |   |  |  |
| Protriptyline<br>Hydrochloride  |  |   |  |  |
| Proxymetacaine<br>Hydrochloride   |  | Non-<br>ophthalmic<br>use   |  |  |
| Pseudoephedrine<br>Hydrochloride  |  | Internal  | (a) In the case of a<br>prolonged release<br>preparation<br>120mg (MD)<br>240mg (MDD)<br>(b) in any other case 60mg<br>(MD)<br>240mg (MDD) |  |
| Pseudoephedrine<br>Sulphate   |  |   | 60mg (MD)<br>180mg (MDD)   |  |
| Pyrantel<br>Embonate  |  | (a) For the<br>treatment of<br>enterobiosis,<br>in adults<br>and children<br>not less than<br>12 years<br><br>(b) For the<br>treatment of<br>enterobiosis,<br>in children<br>less than 12<br>years but<br>not less than<br>6 years<br><br>(c) For the<br>treatment of<br>enterobiosis<br>in children<br>less than 6 | (a) 750mg MDD (as a<br>single dose)<br><br>(b) 500mg MDD (as a<br>single dose)<br><br>(c) 250mg MDD (as a<br>single dose)                  | (a)<br>Container<br>or package<br>containing<br>not more<br>than 750mg<br>of Pyrantel<br>Embonate<br><br>(b)<br>Container<br>or package<br>containing<br>not more<br>than 750mg<br>of Pyrantel<br>Embonate<br><br>(c)<br>Container<br>or package<br>containing<br>not more |

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|---|--------------------------------------|---|---|--------------------------------------|
| <i>Column 1<br/>Substance</i>   | <i>Column 2<br/>Maximum strength</i> | <i>Column 3<br/>Route of administration, use or pharmaceutical form</i> | <i>Column 4<br/>Treatment limitations</i>                                   | <i>Column 5<br/>Maximum quantity</i> |
|   |                                      | years but not less than 2 years   |   | than 750mg of Pyrantel Embonate      |
| Pyrantel Tartrate   |                                      |   |   |                                      |
| Pyrazinamide  |                                      |   |   |                                      |
| Pyridostigmine Bromide  |                                      |   |   |                                      |
| Pyrimethamine   |                                      |   |   |                                      |
| [ <sup>F209</sup> Quetiapine Fumarate]  |                                      |   |   |                                      |
| [ <sup>F194</sup> Quinagolide Hydrochloride]  |                                      |   |   |                                      |
| Quinapril   |                                      |   |   |                                      |
| [ <sup>F255</sup> Quinapril Hydrochloride]  |                                      |   |   |                                      |
| Quinestradol  |                                      |   |   |                                      |
| Quinestrol  |                                      |   |   |                                      |
| Quinethazone  |                                      |   |   |                                      |
| Quinidine   |                                      |   |   |                                      |
| Quinidine Bisulphate  |                                      |   |   |                                      |
| Quinidine Polygalacturonate   |                                      |   |   |                                      |
| Quinidine Sulphate  |                                      |   |   |                                      |
| Quinine   |                                      |   | 100mg (MD)<br>300mg (MDD)   |                                      |
| Quinine Bisulphate  |                                      |   | Equivalent of 100mg of Quinine (MD)<br>Equivalent of 300mg of Quinine (MDD) |                                      |
| Quinine Cinchophen  |                                      |   | Equivalent of 100mg of Quinine (MD)   |                                      |

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| <i>Column 1<br/>Substance</i>   | <i>Column 2<br/>Maximum<br/>strength</i> | <i>Column 3<br/>Route of<br/>administration,<br/>use or<br/>pharmaceutical<br/>form</i> | <i>Column 4<br/>Treatment limitations</i> | <i>Column 5<br/>Maximum<br/>quantity</i> |
|   |  |   | Equivalent of 300mg of Quinine (MDD)      |  |
| Quinine Dihydrochloride   |  |   | Equivalent of 100mg of Quinine (MD)       |  |
|   |  |   | Equivalent of 300mg of Quinine (MDD)      |  |
| Quinine Ethyl Carbonate   |  |   | Equivalent of 100mg of Quinine (MD)       |  |
|   |  |   | Equivalent of 300mg of Quinine (MDD)      |  |
| Quinine Glycerophosphate  |  |   | Equivalent of 100mg of Quinine (MD)       |  |
|   |  |   | Equivalent of 300mg of Quinine (MDD)      |  |
| Quinine Hydrobromide  |  |   | Equivalent of 100mg of Quinine (MD)       |  |
|   |  |   | Equivalent of 300mg of Quinine (MDD)      |  |
| Quinine Hydrochloride   |  |   | Equivalent of 100mg of Quinine (MD)       |  |
|   |  |   | Equivalent of 300mg of Quinine (MDD)      |  |
| Quinine Iodobismuthate  |  |   | Equivalent of 100mg of Quinine (MD)       |  |
|   |  |   | Equivalent of 300mg of Quinine (MDD)      |  |
| Quinine Phosphate   |  |   | Equivalent of 100mg of Quinine (MD)       |  |
|   |  |   | Equivalent of 300mg of Quinine (MDD)      |  |
| Quinine Salicylate  |  |   | Equivalent of 100mg of Quinine (MD)       |  |
|   |  |   | Equivalent of 300mg of Quinine (MDD)      |  |
| Quinine Sulphate  |  |   | Equivalent of 100mg of Quinine (MD)       |  |



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| <i>Column 1<br/>Substance</i>   | <i>Column 2<br/>Maximum<br/>strength</i> | <i>Column 3<br/>Route of<br/>administration,<br/>use or<br/>pharmaceutical<br/>form</i>   | <i>Column 4<br/>Treatment limitations</i>  | <i>Column 5<br/>Maximum<br/>quantity</i> |
| Quinine<br>Tannate  |  |   | Equivalent of 300mg of<br>Quinine (MDD)  |  |
|   |  |   | Equivalent of 100mg of<br>Quinine (MD)   |  |
|   |  |   | Equivalent of 300mg of<br>Quinine (MDD)  |  |
| Quinine in<br>combination<br>with Urea<br>Hydrochloride                                       |  |   |  |  |
| Ramipril  |  |   |  |  |
| [ <sup>193</sup> F<br>Ranitidine<br>Bismuth<br>Citrate]                                       |  |   |  |  |
| Ranitidine<br>Hydrochloride   |  | For the<br>short term<br>symptomatic<br>relief of<br>heartburn,<br>dyspepsia,<br>indigestion,<br>acid<br>indigestion<br>and<br>hyperacidity<br>[ <sup>256</sup> F or the<br>prevention<br>of these<br>symptoms<br>when<br>associated<br>with<br>consuming<br>food and<br>drink] | Equivalent to 75mg of<br>Ranitidine (MD)<br>Equivalent to 300mg of<br>Ranitidine (MDD)<br>For a maximum period of<br>14 days |  |
| Rauwolfia<br>Serpentina   |  |   |  |  |
| Rauwolfia<br>Vomitoria  |  |   |  |  |

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| <i>Column 1<br/>Substance</i>   | <i>Column 2<br/>Maximum<br/>strength</i> | <i>Column 3<br/>Route of<br/>administration,<br/>use or<br/>pharmaceutical<br/>form</i> | <i>Column 4<br/>Treatment limitations</i> | <i>Column 5<br/>Maximum<br/>quantity</i> |
| Razoxane  |  |   |   |  |
| [ <sup>F197</sup> Reboxetine<br>Mesilate]   |  |   |   |  |
| Remoxipride<br>Hydrochloride  |  |   |   |  |
| Reproterol<br>Hydrochloride   |  |   |   |  |
| Rescinnamine  |  |   |   |  |
| Reserpine   |  |   |   |  |
| Rifabutin   |  |   |   |  |
| Rifampicin  |  |   |   |  |
| Rifampicin<br>Sodium  |  |   |   |  |
| Rifamycin   |  |   |   |  |
| [ <sup>F193</sup> Rimexolone]   |  |   |   |  |
| Rimiterol<br>Hydrobromide   |  |   |   |  |
| Risperidone   |  |   |   |  |
| Ritodrine<br>Hydrochloride  |  |   |   |  |
| Rolitetracycline<br>Nitrate   |  |   |   |  |
| [ <sup>F213</sup> Ropinirole<br>Hydrochloride]  |  |   |   |  |
| Sabadilla   |  |   |   |  |
| Salbutamol  |  |   |   |  |
| Salbutamol<br>Sulphate  |  |   |   |  |
| Salcatonin  |  |   |   |  |
| Salcatonin<br>Acetate   |  |   |   |  |
| Salmefamol  |  |   |   |  |

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|---|--------------------------------------|---|---|--------------------------------------|
| <i>Column 1<br/>Substance</i>   | <i>Column 2<br/>Maximum strength</i> | <i>Column 3<br/>Route of administration, use or pharmaceutical form</i> | <i>Column 4<br/>Treatment limitations</i> | <i>Column 5<br/>Maximum quantity</i> |
| Salmeterol Xinafoate  |                                      |   |   |                                      |
| Salsalate   |                                      |   |   |                                      |
| Saralasin Acetate   |                                      |   |   |                                      |
| Selegiline Hydrochloride  |                                      |   |   |                                      |
| Semisodium Valproate  |                                      |   |   |                                      |
| [ <sup>197</sup> F]Sertindole]  |                                      |   |   |                                      |
| [ <sup>193</sup> F]Sertraline Hydrochloride]  |                                      |   |   |                                      |
| Serum Gonadotrophin   |                                      |   |   |                                      |
| [ <sup>193</sup> F]Sevoflurane]   |                                      |   |   |                                      |
| Silver Sulphadiazine  |                                      |   |   |                                      |
| Simvastatin   |                                      |   |   |                                      |
| Sissomicin  |                                      |   |   |                                      |
| Sissomicin Sulphate   |                                      |   |   |                                      |
| Snake Venoms  |                                      |   |   |                                      |
| Sodium Acetrizoate  |                                      |   |   |                                      |
| Sodium Aminosalicylate  |                                      |   |   |                                      |
| Sodium Antimonylgluconate   |                                      |   |   |                                      |
| Sodium Arsanilate   |                                      |   |   |                                      |
| Sodium Arsenate   |                                      |   |   |                                      |

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| <i>Column 1<br/>Substance</i>   | <i>Column 2<br/>Maximum strength</i>   | <i>Column 3<br/>Route of administration, use or pharmaceutical form</i>  | <i>Column 4<br/>Treatment limitations</i> | <i>Column 5<br/>Maximum quantity</i>   |
| Sodium Arsenite   | 0.013 per cent   |  |   |  |
| Sodium Bromide  |  |  |   |  |
| Sodium Clodronate   |  |  |   |  |
| Sodium Cromoglycate   | (a) For nasal administration<br><br>(b) 2.0 per cent<br><br>(c) 4.0 per cent | (a) For nasal administration<br><br>(b) For the treatment of acute seasonal allergic conjunctivitis [F <sup>257</sup> or perennial allergic conjunctivitis]<br><br>In the form of aqueous eye drops<br><br>(c) For the treatment of acute seasonal allergic conjunctivitis<br><br>In the form of an eye ointment |   | (b) Container or package containing not more than 10ml of medicinal product<br><br>(c) Container or package containing not more than 5g of medicinal product |
| Sodium Ethacrynate  |  |  |   |  |
| Sodium Fluoride   | (1) 0.33 per cent  | (1) Dentifrices<br><br>(2) Other preparations for use in the prevention  |   |  |

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|---|--------------------------------------|---|---|--------------------------------------|
| <i>Column 1<br/>Substance</i>   | <i>Column 2<br/>Maximum strength</i> | <i>Column 3<br/>Route of administration, use or pharmaceutical form</i> | <i>Column 4<br/>Treatment limitations</i> | <i>Column 5<br/>Maximum quantity</i> |
|   |                                      | of dental caries  |   |                                      |
|   |                                      | In the form of  |   |                                      |
|   |                                      | (a) tablets or drops  | (a) 2.2 mg (MDD)                          |                                      |
|   | (b) 0.2 per cent                     | (b) mouth rinses other than those for daily use                         |   |                                      |
|   | (c) 0.05 per cent                    | (c) mouth rinses for daily use  |   |                                      |
| Sodium Fusidate   |                                      |   |   |                                      |
| Sodium Metrizoate   |                                      |   |   |                                      |
| Sodium Monofluorophosphate  | 1.14 per cent                        | Dentifrice  |   |                                      |
| Sodium Oxidronate   |                                      |   |   |                                      |
| Sodium Stibogluconate   |                                      |   |   |                                      |
| Sodium Valproate  |                                      |   |   |                                      |
| Somatorelin Acetate   |                                      |   |   |                                      |
| Sotalol Hydrochloride   |                                      |   |   |                                      |
| [ <sup>194</sup> F]Sparfloxacin]  |                                      |   |   |                                      |
| Spectinomycin   |                                      |   |   |                                      |
| Spectinomycin Hydrochloride   |                                      |   |   |                                      |
| Spiramycin  |                                      |   |   |                                      |
| Spiramycin Adipate  |                                      |   |   |                                      |

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|---|--------------------------------------|--|---|--------------------------------------|
| <i>Column 1<br/>Substance</i>   | <i>Column 2<br/>Maximum strength</i> | <i>Column 3<br/>Route of administration,<br/>use or pharmaceutical form</i>  | <i>Column 4<br/>Treatment limitations</i> | <i>Column 5<br/>Maximum quantity</i> |
| Spironolactone  |                                      |  |   |                                      |
| Stannous Fluoride   | ( <sup>F258</sup> 1) 0.62 per cent   | ( <sup>F258</sup> 1) Dentifrice  |   |                                      |
|   | ( <sup>F258</sup> (2) 0.4 per]       | ( <sup>F258</sup> (2) Dental gels for use in the prevention and treatment of dental caries and decalcification of the teeth] |   |                                      |
| Stilboestrol  |                                      |  |   |                                      |
| Stilboestrol Dipropionate   |                                      |  |   |                                      |
| Streptodornase  |                                      | External   |   |                                      |
| Streptokinase   |                                      | External   |   |                                      |
| Streptomycin  |                                      |  |   |                                      |
| Streptomycin Sulphate   |                                      |  |   |                                      |
| Strychnine  |                                      |  |   |                                      |
| Strychnine Arsenate   |                                      |  |   |                                      |
| Strychnine Hydrochloride  |                                      |  |   |                                      |
| [ <sup>F196</sup> Strychnine Nitrate]   |                                      |  |   |                                      |
| Styramate   |                                      |  |   |                                      |
| Succinylsulphathiazole  |                                      |  |   |                                      |
| Sucralfate  |                                      |  |   |                                      |
| Sulbactam   |                                      |  |   |                                      |
| Sodium  |                                      |  |   |                                      |

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|---|--|---|---|--|
| <i>Column 1<br/>Substance</i>   | <i>Column 2<br/>Maximum<br/>strength</i> | <i>Column 3<br/>Route of<br/>administration,<br/>use or<br/>pharmaceutical<br/>form</i> | <i>Column 4<br/>Treatment limitations</i> | <i>Column 5<br/>Maximum<br/>quantity</i> |
| Sulbenicillin   |  |   |   |  |
| Sulbenicillin<br>Sodium   |  |   |   |  |
| Sulconazole<br>Nitrate  |  | External<br>(except<br>vaginal)   |   |  |
| [ <sup>196</sup> F]Sulfabenzamide]  |  |   |   |  |
| Sulfacytine   |  |   |   |  |
| Sulfadoxine   |  |   |   |  |
| Sulfamerazine   |  |   |   |  |
| Sulfamerazine<br>Sodium   |  |   |   |  |
| Sulfametopyrazine   |  |   |   |  |
| Sulfamonomethoxine  |  |   |   |  |
| Sulindac  |  |   |   |  |
| Sulphacetamide  |  |   |   |  |
| Sulphacetamide<br>Sodium  |  |   |   |  |
| Sulphadiazine   |  |   |   |  |
| Sulphadiazine<br>Sodium   |  |   |   |  |
| Sulphadimethoxine   |  |   |   |  |
| Sulphadimidine  |  |   |   |  |
| Sulphadimidine<br>Sodium  |  |   |   |  |
| Sulphafurazole  |  |   |   |  |
| Sulphafurazole<br>Diethanolamine  |  |   |   |  |
| Sulphaguanidine   |  |   |   |  |
| Sulphaloxic<br>Acid   |  |   |   |  |
| Sulphamethizole   |  |   |   |  |

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|---|--|---|---|--|
| <i>Column 1<br/>Substance</i>   | <i>Column 2<br/>Maximum<br/>strength</i> | <i>Column 3<br/>Route of<br/>administration,<br/>use or<br/>pharmaceutical<br/>form</i> | <i>Column 4<br/>Treatment limitations</i> | <i>Column 5<br/>Maximum<br/>quantity</i> |
| Sulphamethoxazole   |  |   |   |  |
| Sulphamethoxydiazine  |  |   |   |  |
| Sulphamethoxypyridazine   |  |   |   |  |
| Sulphamethoxypyridazine<br>Sodium   |  |   |   |  |
| Sulphamoxole  |  |   |   |  |
| Sulphanilamide  |  |   |   |  |
| Sulphaphenazole   |  |   |   |  |
| Sulphapyridine  |  |   |   |  |
| Sulphapyridine<br>Sodium  |  |   |   |  |
| Sulphasalazine  |  |   |   |  |
| Sulphathiazole  |  |   |   |  |
| Sulphathiazole<br>Sodium  |  |   |   |  |
| Sulphaurea  |  |   |   |  |
| Sulphinpyrazone   |  |   |   |  |
| Sulpiride   |  |   |   |  |
| Sultamicillin   |  |   |   |  |
| Sultamicillin<br>Tosylate   |  |   |   |  |
| Sulthiame   |  |   |   |  |
| Sumatriptan<br>Succinate  |  |   |   |  |
| Suprofen  |  |   |   |  |
| Suxamethonium<br>Bromide  |  |   |   |  |
| Suxamethonium<br>Chloride   |  |   |   |  |
| Suxethonium<br>Bromide  |  |   |   |  |



| <i>Exemptions from the restrictions on the sale and supply of prescription only medicines</i> |                                 |   |                              |  |
|---|---------------------------------|---|------------------------------|--|
| <i>Column 1</i>   | <i>Column 2</i>                 | <i>Column 3</i>   | <i>Column 4</i>              | <i>Column 5</i>  |
| <i>Substance</i>  | <i>Maximum strength</i>         | <i>Route of administration, use or pharmaceutical form</i>  | <i>Treatment limitations</i> | <i>Maximum quantity</i>  |
| [ <sup>F209</sup> Tacalcitol Monohydrate]   |                                 |   |                              |  |
| Tacrine Hydrochloride   |                                 |   |                              |  |
| Talampicillin   |                                 |   |                              |  |
| Talampicillin Hydrochloride   |                                 |   |                              |  |
| Talampicillin Napsylate   |                                 |   |                              |  |
| Tamoxifen Citrate   |                                 |   |                              |  |
| [ <sup>F208</sup> Tamsulosin Hydrochloride]   |                                 |   |                              |  |
| [ <sup>F193</sup> Tazarotene]   |                                 |   |                              |  |
| Tazobactam Sodium   |                                 |   |                              |  |
| Teicoplanin   |                                 |   |                              |  |
| [ <sup>F197</sup> Temocapril Hydrochloride]   |                                 |   |                              |  |
| Temocillin Sodium   |                                 |   |                              |  |
| Tenoxicam   |                                 |   |                              |  |
| Terazosin Hydrochloride   |                                 |   |                              |  |
| Terbinafine   | [ <sup>F259</sup> 1.0 per cent] | [ <sup>F260</sup> External use for the treatment of tinea pedis, tinea cruris and tinea corporis. In the form of a gel] |                              | [ <sup>F261</sup> Container or package containing not more than 30 grams of medicinal product] |

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| <i>Exemptions from the restrictions on the sale and supply of prescription only medicines</i> |                                      |  |   |  |
|---|--------------------------------------|--|---|--|
| <i>Column 1<br/>Substance</i>   | <i>Column 2<br/>Maximum strength</i> | <i>Column 3<br/>Route of administration, use or pharmaceutical form</i>  | <i>Column 4<br/>Treatment limitations</i> | <i>Column 5<br/>Maximum quantity</i>   |
| [ <sup>F262</sup> Terbinafin]<br>Hydrochloride]   | [ <sup>F262</sup> 1.0 per cent]      | ( [ <sup>F263</sup> 1])<br>[ <sup>F264</sup> Preparations, other than spray solutions, for]<br>[ <sup>F262</sup> external use for the treatment of tinea pedis and tinea cruris]<br><br>[ <sup>F265</sup> (2)<br>Spray solutions for external use for the treatment of tinea corporis, tinea cruris and tinea pedis] |   | ( [ <sup>F263</sup> 1])<br>[ <sup>F262</sup> Container or package containing not more than 15 g of medicinal product.]<br><br>[ <sup>F265</sup> (2)<br>Container containing not more than 30ml of medicinal product] |
| Terbutaline   |                                      |  |   |  |
| Terbutaline Sulphate  |                                      |  |   |  |
| Terfenadine   |                                      |  | F266                                      | F266   |
|   |                                      |  | ...                                       | ...  |
| Terlipressin  |                                      |  |   |  |
| Terodiline Hydrochloride  |                                      |  |   |  |
| [ <sup>F197</sup> Testosterone]   |                                      |  |   |  |
| Tetrabenazine   |                                      |  |   |  |
| Tetracosactrin Acetate  |                                      |  |   |  |
| Tetracycline  |                                      |  |   |  |

| <i>Exemptions from the restrictions on the sale and supply of prescription only medicines</i> |  |   |   |  |
|---|--|---|---|--|
| <i>Column 1<br/>Substance</i>   | <i>Column 2<br/>Maximum<br/>strength</i> | <i>Column 3<br/>Route of<br/>administration,<br/>use or<br/>pharmaceutical<br/>form</i> | <i>Column 4<br/>Treatment limitations</i> | <i>Column 5<br/>Maximum<br/>quantity</i> |
| Tetracycline Hydrochloride  |  |   |   |  |
| Tetracycline Phosphate Complex  |  |   |   |  |
| Tetroxoprim   |  |   |   |  |
| Thallium Acetate  |  |   |   |  |
| Thallous Chloride   |  |   |   |  |
| Thiabendazole   |  |   |   |  |
| Thiambutosine   |  |   |   |  |
| Thiethylperazine Malate   |  |   |   |  |
| Thiethylperazine Maleate  |  |   |   |  |
| Thiocarlide   |  |   |   |  |
| Thioguanine   |  |   |   |  |
| Thiopentone Sodium  |  |   |   |  |
| Thiopropazate Hydrochloride   |  |   |   |  |
| Thioproperazine Mesylate  |  |   |   |  |
| Thioridazine  |  |   |   |  |
| Thioridazine Hydrochloride  |  |   |   |  |
| Thiosinamine  |  |   |   |  |
| Thiotepa  |  |   |   |  |
| Thiothixene   |  |   |   |  |
| Thiouracil  |  |   |   |  |
| Thymoxamine Hydrochloride   |  |   |   |  |
| Thyroid   |  |   |   |  |

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**Changes to legislation:** There are currently no known outstanding effects for the The Prescription Only Medicines (Human Use) Order 1997. (See end of Document for details)

| <i>Exemptions from the restrictions on the sale and supply of prescription only medicines</i> |  |   |   |  |
|---|--|---|---|--|
| <i>Column 1<br/>Substance</i>   | <i>Column 2<br/>Maximum<br/>strength</i> | <i>Column 3<br/>Route of<br/>administration,<br/>use or<br/>pharmaceutical<br/>form</i> | <i>Column 4<br/>Treatment limitations</i> | <i>Column 5<br/>Maximum<br/>quantity</i> |
| Thyrotrophin  |  |   |   |  |
| Thyroxine<br>Sodium   |  |   |   |  |
| Tiamulin<br>Fumarate  |  |   |   |  |
| Tiaprofenic<br>Acid   |  |   |   |  |
| Tibolone  |  |   |   |  |
| Ticarcillin<br>Sodium   |  |   |   |  |
| [ <sup>F208</sup> Ticlopidine<br>Hydrochloride]   |  |   |   |  |
| Tigloidine<br>Hydrobromide  |  |   |   |  |
| [ <sup>F208</sup> Tiludronate<br>Disodium]  |  |   |   |  |
| Timolol<br>Maleate  |  |   |   |  |
| Tinidazole  |  |   |   |  |
| Tinzaparin  |  |   |   |  |
| Tioconazole   | (1) 2.0 per cent                         | (1) External (except vaginal)<br><br>(2) Vaginal for treatment of vaginal candidiasis   |   |  |
| [ <sup>F194</sup> Tizanidine<br>Hydrochloride]  |  |   |   |  |
| Tobramycin  |  |   |   |  |
| Tobramycin<br>Sulphate  |  |   |   |  |
| Tocainide<br>Hydrochloride  |  |   |   |  |

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| <i>Exemptions from the restrictions on the sale and supply of prescription only medicines</i> |  |   |   |   |
|---|--|---|---|---|
| <i>Column 1<br/>Substance</i>   | <i>Column 2<br/>Maximum<br/>strength</i> | <i>Column 3<br/>Route of<br/>administration,<br/>use or<br/>pharmaceutical<br/>form</i> | <i>Column 4<br/>Treatment limitations</i> | <i>Column 5<br/>Maximum<br/>quantity</i>  |
| Tofenacin<br>Hydrochloride  |  |   |   |   |
| Tolazamide  |  |   |   |   |
| Tolazoline<br>Hydrochloride   |  | External  |   |   |
| Tolbutamide   |  |   |   |   |
| Tolbutamide<br>Sodium   |  |   |   |   |
| Tolfenamic<br>Acid  |  |   |   |   |
| Tolmetin<br>Sodium  |  |   |   |   |
| [ <sup>F193</sup> Topiramate]   |  |   |   |   |
| [ <sup>F218</sup> Torasemide]   |  |   |   |   |
| [ <sup>F208</sup> Toremifene]   |  |   |   |   |
| Tramadol<br>Hydrochloride   |  |   |   |   |
| Trandolapril  |  |   |   |   |
| Tranexamic<br>Acid  |  |   |   |   |
| Tranlycypromine<br>Sulphate   |  |   |   |   |
| Trazodone<br>Hydrochloride  |  |   |   |   |
| Treosulfan  |  |   |   |   |
| Tretinoin   |  |   |   |   |
| Triamcinolone<br>Acetonide  | [ <sup>F267</sup> (1)] 0.1<br>per cent   | [ <sup>F267</sup> (1)]<br>For the<br>treatment<br>of common<br>mouth<br>ulcers          |   | [ <sup>F267</sup> (1)]<br>Container<br>or package<br>containing<br>not more<br>than 5g of |

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| <i>Exemptions from the restrictions on the sale and supply of prescription only medicines</i> |                                      |  |  |   |
|---|--------------------------------------|--|--|---|
| <i>Column 1<br/>Substance</i>   | <i>Column 2<br/>Maximum strength</i> | <i>Column 3<br/>Route of administration, use or pharmaceutical form</i>  | <i>Column 4<br/>Treatment limitations</i>  | <i>Column 5<br/>Maximum quantity</i>  |
|   |                                      |  |  | medicinal product   |
|   |                                      | [ <sup>F268</sup> (2) In the form of a non-pressurised nasal spray, for the treatment of symptoms of seasonal allergic rhinitis in persons aged 18 years and over] | [ <sup>F268</sup> (2) 110mcg per nostril (MD)<br>110mcg per nostril (MDD)<br>For a maximum period of 3 months] | [ <sup>F268</sup> Container or package containing not more than 3.575mg of Triamcinolone Acetonide] |
| Triamcinolone Diacetate   |                                      |  |  |   |
| Triamcinolone Hexacetonide  |                                      |  |  |   |
| Triamterene   |                                      |  |  |   |
| Tribavirin  |                                      |  |  |   |
| Triclofos Sodium  |                                      |  |  |   |
| Trientine Dihydrochloride   |                                      |  |  |   |
| Trifluoperazine   |                                      |  |  |   |
| Trifluoperazine Hydrochloride   |                                      |  |  |   |
| Trifluoperidol  |                                      |  |  |   |
| Trifluoperidol Hydrochloride  |                                      |  |  |   |
| Trilostane  |                                      |  |  |   |
| Trimeprazine  |                                      |  |  |   |
| Trimeprazine Tartrate   |                                      |  |  |   |

| <i>Exemptions from the restrictions on the sale and supply of prescription only medicines</i> |  |   |   |  |
|---|--|---|---|--|
| <i>Column 1<br/>Substance</i>   | <i>Column 2<br/>Maximum<br/>strength</i> | <i>Column 3<br/>Route of<br/>administration,<br/>use or<br/>pharmaceutical<br/>form</i> | <i>Column 4<br/>Treatment limitations</i> | <i>Column 5<br/>Maximum<br/>quantity</i> |
| Trimetaphan<br>Camsylate  |  |   |   |  |
| Trimetazidine   |  |   |   |  |
| Trimetazidine<br>Hydrochloride  |  |   |   |  |
| Trimethoprim  |  |   |   |  |
| Trimipramine<br>Maleate   |  |   |   |  |
| Trimipramine<br>Mesylate  |  |   |   |  |
| Tropicamide   |  |   |   |  |
| Tropisetron<br>Hydrochloride  |  |   |   |  |
| Troxidone   |  |   |   |  |
| L-<br>Tryptophan  |  | (1) Oral<br>Dietary<br>supplementation<br>(2) External                                  |   |  |
| Tubocurarine<br>Chloride  |  |   |   |  |
| Tulobuterol   |  |   |   |  |
| Tulobuterol<br>Hydrochloride  |  |   |   |  |
| Tyrothricin   |  | Throat<br>lozenges<br>or throat<br>pastilles  |   |  |
| Uramustine  |  |   |   |  |
| Urea<br>Stibamine   |  |   |   |  |
| Urethane  |  |   |   |  |
| Uridine 5'-<br>triphosphate   |  |   |   |  |
| Urofollitrophin   |  |   |   |  |

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| <i>Exemptions from the restrictions on the sale and supply of prescription only medicines</i> |  |   |   |  |
|---|--|---|---|--|
| <i>Column 1<br/>Substance</i>   | <i>Column 2<br/>Maximum<br/>strength</i> | <i>Column 3<br/>Route of<br/>administration,<br/>use or<br/>pharmaceutical<br/>form</i> | <i>Column 4<br/>Treatment limitations</i> | <i>Column 5<br/>Maximum<br/>quantity</i> |
| Urokinase   |  |   |   |  |
| Ursodeoxychoic<br>Acid  |  |   |   |  |
| Vaccine:<br>Bacillus<br>Salmonella<br>Typhi   |  |   |   |  |
| Vaccine:<br>Poliomyelitis<br>(Oral)   |  |   |   |  |
| [ <sup>F194</sup> Valaciclovir<br>Hydrochloride]  |  |   |   |  |
| Valproic<br>Acid  |  |   |   |  |
| [ <sup>F197</sup> Valsartan]  |  |   |   |  |
| Vancomycin<br>Hydrochloride   |  |   |   |  |
| Vasopressin   |  |   |   |  |
| Vasopressin<br>Tannate  |  |   |   |  |
| Vecuronium<br>Bromide   |  |   |   |  |
| [ <sup>F194</sup> Venlafaxine<br>Hydrochloride]   |  |   |   |  |
| Verapamil<br>Hydrochloride  |  |   |   |  |
| Veratrine   |  |   |   |  |
| Veratrum,<br>Green  |  |   |   |  |
| Veratrum,<br>White  |  |   |   |  |
| Vidarabine  |  |   |   |  |
| Vigabatrin  |  |   |   |  |
| Viloxazine<br>Hydrochloride   |  |   |   |  |



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| <i>Exemptions from the restrictions on the sale and supply of prescription only medicines</i> |                                      |   |   |                                      |
|---|--------------------------------------|---|---|--------------------------------------|
| <i>Column 1<br/>Substance</i>   | <i>Column 2<br/>Maximum strength</i> | <i>Column 3<br/>Route of administration, use or pharmaceutical form</i> | <i>Column 4<br/>Treatment limitations</i>                               | <i>Column 5<br/>Maximum quantity</i> |
| Vinblastine Sulphate  |                                      |   |   |                                      |
| Vincristine Sulphate  |                                      |   |   |                                      |
| Vindesine Sulphate  |                                      |   |   |                                      |
| Viomycin Pantothenate   |                                      |   |   |                                      |
| Viomycin Sulphate   |                                      |   |   |                                      |
| Vitamin A   |                                      | (1) Internal  | (1) 7,500iu (2,250mcg Retinol equivalent) (MDD)                         |                                      |
|   |                                      | (2) External  |   |                                      |
| Vitamin A Acetate   |                                      | (1) Internal  | (1) Equivalent to 7,500iu Vitamin A (2,250mcg Retinol equivalent) (MDD) |                                      |
|   |                                      | (2) External  |   |                                      |
| Vitamin A Palmitate   |                                      | (1) Internal  | (1) Equivalent to 7,500iu Vitamin A (2,250mcg Retinol equivalent) (MDD) |                                      |
|   |                                      | (2) External  |   |                                      |
| Warfarin  |                                      |   |   |                                      |
| Warfarin Sodium   |                                      |   |   |                                      |
| Xamoterol Fumarate  |                                      |   |   |                                      |
| Xipamide  |                                      |   |   |                                      |
| Yohimbine Hydrochloride   |                                      |   |   |                                      |
| [ <sup>194</sup> F]Zalcitabine]   |                                      |   |   |                                      |
| Zidovudine  |                                      |   |   |                                      |

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| <i>Exemptions from the restrictions on the sale and supply of prescription only medicines</i> |                         |  |                              |                         |
|---|-------------------------|--|------------------------------|-------------------------|
| <i>Column 1</i>   | <i>Column 2</i>         | <i>Column 3</i>  | <i>Column 4</i>              | <i>Column 5</i>         |
| <i>Substance</i>  | <i>Maximum strength</i> | <i>Route of administration, use or pharmaceutical form</i> | <i>Treatment limitations</i> | <i>Maximum quantity</i> |
| Zimeldine Hydrochloride   |                         |  |                              |                         |
| Zolpidem Tartrate   |                         |  |                              |                         |
| Zomepirac Sodium  |                         |  |                              |                         |
| Zopiclone   |                         |  |                              |                         |
| Zuclopenthixol Acetate  |                         |  |                              |                         |
| Zuclopenthixol Decanoate  |                         |  |                              |                         |
| Zuclopenthixol Hydrochloride]   |                         |  |                              |                         |

#### Textual Amendments

- F193** Words in Sch. 1 inserted (9.8.2000) by The Prescription Only Medicines (Human Use) Amendment Order 2000 (S.I. 2000/1917), arts. 1(1), **3(c)**
- F194** Words in Sch. 1 inserted (19.1.2000) by The Prescription Only Medicines (Human Use) Amendment (No. 2) Order 1999 (S.I. 1999/3463), arts. 1(1), **2(c)**
- F195** Words in Sch. 1 inserted (24.8.2001) by The Prescription Only Medicines (Human Use) Amendment Order 2001 (S.I. 2001/2777), arts. 1(1), **3(a)**
- F196** Words in Sch. 1 inserted (16.9.1998) by The Prescription Only Medicines (Human Use) Amendment (No. 3) Order 1998 (S.I. 1998/2081), art. 1(1), **Sch.**
- F197** Sch. 1 entries inserted (24.8.2001) by The Prescription Only Medicines (Human Use) Amendment Order 2001 (S.I. 2001/2777), arts. 1(1), **3(g)**
- F198** Words in Sch. 1 inserted (16.9.1998) by The Prescription Only Medicines (Human Use) Amendment Order 1997 (S.I. 1997/2044), art. 1(1), **Sch. 1**
- F199** Words in Sch. 1 inserted (22.4.1999) by The Prescription Only Medicines (Human Use) Amendment Order 1999 (S.I. 1999/1044), arts. 1(1), **2(a)**
- F200** Words in Sch. 1 substituted (16.9.1998) by The Prescription Only Medicines (Human Use) Amendment (No. 3) Order 1998 (S.I. 1998/2081), arts. 1(1), **3(a)**
- F201** Sch. 1: entries renumbered (22.4.1999) by The Prescription Only Medicines (Human Use) Amendment Order 1999 (S.I. 1999/1044), arts. 1(1), **2(a)**
- F202** Words in Sch. 1 omitted (16.9.1998) by virtue of The Prescription Only Medicines (Human Use) Amendment (No. 3) Order 1998 (S.I. 1998/2081), arts. 1(1), **3(b)**
- F203** Words in Sch. 1 inserted (16.11.2000) by The Prescription Only Medicines (Human Use) Amendment (No. 2) Order 2000 (S.I. 2000/2899), arts. 1(1), **4(a)**
- F204** Words in Sch. 1 substituted (16.11.2000) by The Prescription Only Medicines (Human Use) Amendment (No. 2) Order 2000 (S.I. 2000/2899), arts. 1(1), **4(a)**

- F205** Word in Sch. 1 substituted (22.4.1999) by The Prescription Only Medicines (Human Use) Amendment Order 1999 (S.I. 1999/1044), arts. 1(1), **2(b)**
- F206** Words in Sch. 1 inserted (16.9.1998) by The Prescription Only Medicines (Human Use) Amendment (No. 3) Order 1998 (S.I. 1998/2081), arts. 1(1), **3(c)(ii)**
- F207** Words in Sch. 1 substituted (16.9.1998) by virtue of The Prescription Only Medicines (Human Use) Amendment (No. 3) Order 1998 (S.I. 1998/2081), arts. 1(1), **3(c)(i)**
- F208** Words in Sch. 1 inserted (16.11.2000) by The Prescription Only Medicines (Human Use) Amendment (No. 2) Order 2000 (S.I. 2000/2899), arts. 1(1), **4(h)**
- F209** Words in Sch. 1 inserted (22.4.1999) by The Prescription Only Medicines (Human Use) Amendment Order 1999 (S.I. 1999/1044), arts. 1(1), **2(e)**
- F210** Word in Sch. 1 substituted (16.9.1997) by The Prescription Only Medicines (Human Use) Amendment Order 1997 (S.I. 1997/2044), arts. 1(1), **2(a)**
- F211** Words in Sch. 1 revoked (31.12.2001) by The Prescription Only Medicines (Human Use) Amendment (No. 2) Order 2001 (S.I. 2001/3942), arts. 1(1), **2(a)**
- F212** Sch. 1 entries inserted (24.8.2001) by The Prescription Only Medicines (Human Use) Amendment Order 2001 (S.I. 2001/2777), arts. 1(1), **3(f)**
- F213** Sch. 1 entries inserted (31.12.2001) by The Prescription Only Medicines (Human Use) Amendment (No. 2) Order 2001 (S.I. 2001/3942), arts. 1(1), **2(e)**
- F214** Sch. 1 entries inserted (16.11.2000) by The Prescription Only Medicines (Human Use) Amendment (No. 2) Order 2000 (S.I. 2000/2899), arts. 1(1), **4(b)**
- F215** Words in Sch. 1 inserted (1.6.1998) by The Prescription Only Medicines (Human Use) Amendment (No. 2) Order 1998 (S.I. 1998/1178), arts. 1(1), **2(a)**
- F216** Words in Sch. 1 substituted (16.9.1998) by The Prescription Only Medicines (Human Use) Amendment (No. 3) Order 1998 (S.I. 1998/2081), arts. 1(1), **3(d)**
- F217** Words in Sch. 1 substituted (16.11.2000) by The Prescription Only Medicines (Human Use) Amendment (No. 2) Order 2000 (S.I. 2000/2899), arts. 1(1), **4(c)**
- F218** Words in Sch. 1 inserted (13.2.1998) by The Prescription Only Medicines (Human Use) Amendment Order 1998 (S.I. 1998/108), arts. 1, **3(e)(i)**
- F219** Word in Sch. 1 substituted (19.1.2000) by The Prescription Only Medicines (Human Use) Amendment (No. 2) Order 1999 (S.I. 1999/3463), arts. 1(1), **2(a)**
- F220** Words in Sch. 1 substituted (16.9.1998) by The Prescription Only Medicines (Human Use) Amendment (No. 3) Order 1998 (S.I. 1998/2081), arts. 1(1), **3(e)**
- F221** Words in Sch. 1 inserted (24.8.2001) by The Prescription Only Medicines (Human Use) Amendment Order 2001 (S.I. 2001/2777), arts. 1(1), **3(b)**
- F222** Words in Sch. 1 substituted (16.9.1998) by The Prescription Only Medicines (Human Use) Amendment (No. 3) Order 1998 (S.I. 1998/2081), arts. 1(1), **3(f)(i)**
- F223** Words in Sch. 1 inserted (16.9.1998) by The Prescription Only Medicines (Human Use) Amendment (No. 3) Order 1998 (S.I. 1998/2081), arts. 1(1), **3(f)(ii)**
- F224** Words in Sch. 1 omitted (16.9.1998) by virtue of The Prescription Only Medicines (Human Use) Amendment (No. 3) Order 1998 (S.I. 1998/2081), arts. 1(1), **3(f)(iii)**
- F225** Words in Sch. 1 inserted (31.12.2001) by The Prescription Only Medicines (Human Use) Amendment (No. 2) Order 2001 (S.I. 2001/3942), arts. 1(1), **2(b)(i)**
- F226** Words in Sch. 1 inserted (31.12.2001) by The Prescription Only Medicines (Human Use) Amendment (No. 2) Order 2001 (S.I. 2001/3942), arts. 1(1), **2(b)(ii)**
- F227** Words in Sch. 1 inserted (31.12.2001) by The Prescription Only Medicines (Human Use) Amendment (No. 2) Order 2001 (S.I. 2001/3942), arts. 1(1), **2(b)(iii)**
- F228** Words in Sch. 1 inserted (31.12.2001) by The Prescription Only Medicines (Human Use) Amendment (No. 2) Order 2001 (S.I. 2001/3942), arts. 1(1), **2(b)(iv)**
- F229** Words in Sch. 1 inserted (22.4.1999) by The Prescription Only Medicines (Human Use) Amendment Order 1999 (S.I. 1999/1044), arts. 1(1), **2(e)**
- F230** Sch. 1: entries renumbered (22.4.1999) by The Prescription Only Medicines (Human Use) Amendment Order 1999 (S.I. 1999/1044), arts. 1(1), **2(e)**

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*Changes to legislation: There are currently no known outstanding effects for the The Prescription Only Medicines (Human Use) Order 1997. (See end of Document for details)*

- F231** Words in Sch. 1 inserted (13.2.1998) by The Prescription Only Medicines (Human Use) Amendment Order 1998 (S.I. 1998/108), arts. 1, **3(a)**
- F232** Words in Sch. 1 inserted (24.8.2001) by The Prescription Only Medicines (Human Use) Amendment Order 2001 (S.I. 2001/2777), arts. 1(1), **3(c)**
- F233** Words in Sch. 1 inserted (9.8.2000) by The Prescription Only Medicines (Human Use) Amendment Order 2000 (S.I. 2000/1917), arts. 1(1), **3(a)**
- F234** Words in Sch. 1 substituted (16.11.2000) by The Prescription Only Medicines (Human Use) Amendment (No. 2) Order 2000 (S.I. 2000/2899), arts. 1(1), **4(d)**
- F235** Word in Sch. 1 inserted (13.8.1998) by The Prescription Only Medicines (Human Use) Amendment Order 1998 (S.I. 1998/108), arts. 1, **3(e)(ii)**
- F236** Word in Sch. 1 inserted (16.9.1998) by The Prescription Only Medicines (Human Use) Amendment (No. 3) Order 1998 (S.I. 1998/2081), arts. 1(1), **3(g)(ii)**
- F237** Words in Sch. 1 inserted (16.9.1998) by The Prescription Only Medicines (Human Use) Amendment (No. 3) Order 1998 (S.I. 1998/2081), arts. 1(1), **3(g)(i)**
- F238** Words in Sch. 1 inserted (16.9.1998) by The Prescription Only Medicines (Human Use) Amendment (No. 3) Order 1998 (S.I. 1998/2081), arts. 1(1), **3(g)(iii)**
- F239** Words in Sch. 1 inserted (19.1.2000) by The Prescription Only Medicines (Human Use) Amendment (No. 2) Order 1999 (S.I. 1999/3463), arts. 1(1), **2(b)**
- F240** Sch. 1 entries inserted (1.1.2001) by The Prescription Only Medicines (Human Use) Amendment (No. 3) Order 2000 (S.I. 2000/3231), arts. 1(1), **2**
- F241** Words in Sch. 1 inserted (16.11.2000) by The Prescription Only Medicines (Human Use) Amendment (No. 2) Order 2000 (S.I. 2000/2899), arts. 1(1), **4(e)(i)**
- F242** Words in Sch. 1 inserted (16.11.2000) by The Prescription Only Medicines (Human Use) Amendment (No. 2) Order 2000 (S.I. 2000/2899), arts. 1(1), **4(e)(ii)**
- F243** Words in Sch. 1 revoked (31.12.2001) by The Prescription Only Medicines (Human Use) Amendment (No. 2) Order 2001 (S.I. 2001/3942), arts. 1(1), **2(c)**
- F244** Words in Sch. 1 substituted (13.2.1998) by The Prescription Only Medicines (Human Use) Amendment Order 1998 (S.I. 1998/108), arts. 1, **3(b)**
- F245** Words in Sch. 1 substituted (1.6.1998) by The Prescription Only Medicines (Human Use) Amendment (No. 2) Order 1998 (S.I. 1998/1178), arts. 1(1), **2(b)**
- F246** Words in Sch. 1 inserted (16.9.1998) by The Prescription Only Medicines (Human Use) Amendment (No. 3) Order 1998 (S.I. 1998/2081), arts. 1(1), **3(h)**
- F247** Words in Sch. 1 inserted (1.6.1998) by The Prescription Only Medicines (Human Use) Amendment (No. 2) Order 1998 (S.I. 1998/1178), arts. 1(1), **2(c)(i)**
- F248** Words in Sch. 1 inserted (1.6.1998) by The Prescription Only Medicines (Human Use) Amendment (No. 2) Order 1998 (S.I. 1998/1178), arts. 1(1), **2(c)(ii)**
- F249** Words in Sch. 1 substituted (1.6.1998) by The Prescription Only Medicines (Human Use) Amendment (No. 2) Order 1998 (S.I. 1998/1178), arts. 1(1), **2(c)(iii)**
- F250** Words in Sch. 1 inserted (22.4.1999) by The Prescription Only Medicines (Human Use) Amendment Order 1999 (S.I. 1999/1044), arts. 1(1), **2(d)**
- F251** Words in Sch. 1 substituted (16.11.2000) by The Prescription Only Medicines (Human Use) Amendment (No. 2) Order 2000 (S.I. 2000/2899), arts. 1(1), **4(f)(i)**
- F252** Words in Sch. 1 inserted (16.11.2000) by The Prescription Only Medicines (Human Use) Amendment (No. 2) Order 2000 (S.I. 2000/2899), arts. 1(1), **4(f)(ii)**
- F253** Words in Sch. 1 inserted (16.11.2000) by The Prescription Only Medicines (Human Use) Amendment (No. 2) Order 2000 (S.I. 2000/2899), arts. 1(1), **4(f)(iii)**
- F254** Words in Sch. 1 inserted (16.9.1998) by The Prescription Only Medicines (Human Use) Amendment (No. 2) Order 1998 (S.I. 1998/1178), arts. 1(1), **2(d)(ii)**
- F255** Words in Sch. 1 inserted (1.6.1998) by The Prescription Only Medicines (Human Use) Amendment (No. 2) Order 1998 (S.I. 1998/1178), arts. 1(1), **2(d)(i)**
- F256** Words in Sch. 1 added (13.2.1998) by The Prescription Only Medicines (Human Use) Amendment Order 1998 (S.I. 1998/108), arts. 1, **3(c)**

- F257** Words in Sch. 1 inserted (13.2.1998) by The Prescription Only Medicines (Human Use) Amendment Order 1998 (S.I. 1998/108), arts. 1, **3(d)**
- F258** Sch. 1: entries renumbered (24.8.2001) by The Prescription Only Medicines (Human Use) Amendment Order 2001 (S.I. 2001/2777), arts. 1(1), **3(d)**
- F259** Words in Sch. 1 inserted (31.12.2001) by The Prescription Only Medicines (Human Use) Amendment (No. 2) Order 2001 (S.I. 2001/3942), arts. 1(1), **2(d)(i)**
- F260** Words in Sch. 1 inserted (31.12.2001) by The Prescription Only Medicines (Human Use) Amendment (No. 2) Order 2001 (S.I. 2001/3942), arts. 1(1), **2(d)(ii)**
- F261** Words in Sch. 1 inserted (31.12.2001) by The Prescription Only Medicines (Human Use) Amendment (No. 2) Order 2001 (S.I. 2001/3942), arts. 1(1), **2(d)(iii)**
- F262** Words in Sch. 1 inserted (9.8.2000) by The Prescription Only Medicines (Human Use) Amendment Order 2000 (S.I. 2000/1917), arts. 1(1), **3(b)**
- F263** Sch. 1: entries renumbered (24.8.2001) by The Prescription Only Medicines (Human Use) Amendment Order 2001 (S.I. 2001/2777), arts. 1(1), **3(e)**
- F264** Words in Sch. 1 inserted (24.8.2001) by The Prescription Only Medicines (Human Use) Amendment Order 2001 (S.I. 2001/2777), arts. 1(1), **3(e)**
- F265** Sch. 1 entries inserted (24.8.2001) by The Prescription Only Medicines (Human Use) Amendment Order 2001 (S.I. 2001/2777), arts. 1(1), **3(e)**
- F266** Words in Sch. 1 omitted (16.9.1997) by virtue of The Prescription Only Medicines (Human Use) Amendment Order 1997 (S.I. 1997/2044), arts. 1(1), **2(b)**
- F267** Sch. 1 entries re-numbered (16.11.2000) by The Prescription Only Medicines (Human Use) Amendment (No. 2) Order 2000 (S.I. 2000/2899), arts. 1(1), **4(g)**
- F268** Sch. 1 entries inserted (16.11.2000) by The Prescription Only Medicines (Human Use) Amendment (No. 2) Order 2000 (S.I. 2000/2899), arts. 1(1), **4(g)**

[<sup>F269</sup>SCHEDULE 2

Article 10(1)

SUBSTANCES WHICH MAY BE EXCLUDED FROM THE CLASS  
OF PRESCRIPTION ONLY MEDICINES AT HIGH DILUTION

**Textual Amendments**

- F269** Sch. 2 substituted (1.5.2006) by The Medicines for Human Use (Prescribing) (Miscellaneous Amendments) Order 2006 (S.I. 2006/915), arts. 1(1), **12**

Codeine and its salts  
Dihydrocodeine and its salts  
Ethylmorphine and its salts  
Morphine and its salts  
Medicinal Opium  
Pholcodine and its salts]

Status: Point in time view as at 17/01/2011.

Changes to legislation: There are currently no known outstanding effects for the The Prescription Only Medicines (Human Use) Order 1997. (See end of Document for details)

SCHEDULE 3

Article 2(b)

DESCRIPTIONS AND CLASSES OF PRESCRIPTION ONLY MEDICINES IN RELATION TO WHICH [F270 community practitioner nurse prescribers] ARE APPROPRIATE PRACTITIONERS

Textual Amendments

F270 Words in Sch. 3 heading substituted (1.5.2006) by The Medicines for Human Use (Prescribing) (Miscellaneous Amendments) Order 2006 (S.I. 2006/915), arts. 1(1), 13

- [F271 Co-danthramer Capsules NPF]
- [F271 Co-danthramer Capsules, Strong NPF]
- Co-danthramer-Oral Suspension NPF
- Co-danthramer-Oral Suspension Strong NPF
- Co-danthrusate Capsules
- [F271 Co-danthrusate Oral Suspension NPF]
- Mebendazole Tablets NPF
- Mebendazole Oral Suspension NPF
- Miconazole Oral Gel NPF
- Nystatin Oral Suspension
- Nystatin Pastilles NPF
- Streptokinase and Streptodornase Topical Powder NPF
- [F272 Water for Injections]

Textual Amendments

- F271 Words in Sch. 3 inserted (13.2.1998) by The Prescription Only Medicines (Human Use) Amendment Order 1998 (S.I. 1998/108), arts. 1, 4
- F272 Words in Sch. 3 inserted (4.4.2003) by The Prescription Only Medicines (Human Use) Amendment Order 2003 (S.I. 2003/696), arts. 1(1), 14

F273 SCHEDULE 3A

Article 3A

CONTROLLED DRUGS WHICH MAY BE PRESCRIBED, ADMINISTERED OR DIRECTED FOR ADMINISTRATION BY NURSE INDEPENDENT PRESCRIBERS AND CONDITIONS FOR SUCH PRESCRIPTION OR ADMINISTRATION

Textual Amendments

F273 Sch. 3A omitted (1.4.2008) by virtue of The Prescription Only Medicines (Human Use) Amendment Order 2008 (S.I. 2008/464), arts. 1(1), 10

[<sup>F274</sup>SCHEDULE 3B

Regulation 3B(3)(a)(iii)

PARTICULARS FOR CLINICAL MANAGEMENT PLANS

**Textual Amendments**

**F274** Sch. 3B inserted (4.4.2003) by [The Prescription Only Medicines \(Human Use\) Amendment Order 2003 \(S.I. 2003/696\)](#), arts. 1(1), 16

A clinical management plan shall contain the following particulars—

- (a) the name of the patient to whom the plan relates;
- (b) the illnesses or conditions which may be treated by the supplementary prescriber;
- (c) the date on which the plan is to take effect and when it is to be reviewed by the doctor or dentist who is a party to the plan;
- (d) reference to the class or description of medicinal product which may be prescribed or administered under the plan;
- (e) any restrictions or limitations as to the strength or dose of any product which may be prescribed or administered under the plan, and any period of administration or use of any medicinal product which may be prescribed or administered under the plan;
- (f) relevant warnings about the known sensitivities of the patient to, or known difficulties of the patient with, particular medicinal products;
- (g) the arrangements for notification of—
  - (i) suspected or known adverse reactions to any medicinal product which may be prescribed or administered under the plan, and
  - (ii) suspected or known adverse reactions to any other medicinal product taken at the same time as any medicinal product prescribed or administered under the plan; and
- (h) the circumstances in which the supplementary prescriber should refer to, or seek the advice of, the doctor or dentist who is a party to the plan.]

SCHEDULE 4

Article 8(4)(c)

SUBSTANCES NOT TO BE CONTAINED IN A PRESCRIPTION ONLY MEDICINE SOLD OR SUPPLIED UNDER THE EXEMPTION CONFERRED BY ARTICLE 8(3)

Ammonium Bromide  
Calcium Bromide  
Calcium Bromidolactobionate  
Embutramide  
Fencamfamin Hydrochloride  
Fluanisone  
Hexobarbitone  
Hexobarbitone Sodium  
Hydrobromic Acid  
Meclofenoxate Hydrochloride

**Status:** Point in time view as at 17/01/2011.

**Changes to legislation:** There are currently no known outstanding effects for the The Prescription Only Medicines (Human Use) Order 1997. (See end of Document for details)

- Methohexitone Sodium
- Pemoline
- Piracetam
- Potassium Bromide
- Prolintane Hydrochloride
- Sodium Bromide
- Strychnine Hydrochloride
- Tacrine Hydrochloride
- Thiopentone Sodium

SCHEDULE 5

Article 11(1)(a)

EXEMPTION FOR CERTAIN PERSONS FROM SECTION 58(2) OF THE ACT

PART I

EXEMPTION FROM RESTRICTIONS ON SALE OR SUPPLY

| <i>Column 1</i><br><i>Persons exempted</i>   | <i>Column 2</i><br><i>Prescription only medicines to which the exemption applies</i> | <i>Column 3</i><br><i>Conditions</i>  |
|--|--|---|
| 1. Persons selling or supplying prescription only medicines to universities, other institutions concerned with higher education or institutions concerned with research. | 1. All prescription only medicines   | 1. The sale or supply shall be—<br>(a) subject to the presentation of an order signed by the principal of the institution concerned with education or research or the appropriate head of department in charge of a specified course of research stating—<br>(i) the name of the institution for which the prescription only medicine is required,<br>(ii) the purpose for which the prescription only medicine |



**Status:** Point in time view as at 17/01/2011.

**Changes to legislation:** There are currently no known outstanding effects for the The Prescription Only Medicines (Human Use) Order 1997. (See end of Document for details)

| <i>Column 1</i><br><i>Persons exempted</i>  | <i>Column 2</i><br><i>Prescription only medicines to which the exemption applies</i> | <i>Column 3</i><br><i>Conditions</i>   |
|---|--|--|
| <p>2. Persons selling or supplying prescription only medicines to any of the following—</p> <ul style="list-style-type: none"> <li>(1) a public analyst appointed under section 27 of the Food Safety Act 1990<sup>(15)</sup> or article 36 of the Food (Northern Ireland) Order 1989<sup>(16)</sup>,</li> <li>(2) an authorized officer within the meaning of section 5(6) of the Food Safety Act 1990,</li> <li>(3) a sampling officer within the meaning of article 38(1) of the Food (Northern Ireland) Order 1989,</li> <li>(4) a person duly authorized by an enforcement authority under sections 111 and 112,</li> <li>(5) a sampling officer within the meaning of Schedule 3 to the Act.</li> </ul> | <p>2. All prescription only medicines.</p>   | <p>is required, and</p> <ul style="list-style-type: none"> <li>(iii) the total quantity required, and</li> <li>(b) for the purposes of the education or research with which the institution is concerned.</li> </ul> <p>2. The sale or supply shall be subject to the presentation of an order signed by or on behalf of any person listed in column 1 of this paragraph stating the status of the person signing it and the amount of prescription only medicine required, and shall be only in connection with the exercise by those persons of their statutory functions.</p> |

<sup>(15)</sup> 1990 c. 16.

<sup>(16)</sup> S.I. 1989/846 (N.I. 6).

**Status:** Point in time view as at 17/01/2011.

**Changes to legislation:** There are currently no known outstanding effects for the The Prescription Only Medicines (Human Use) Order 1997. (See end of Document for details)

| <i>Column 1</i><br><i>Persons exempted</i>  | <i>Column 2</i><br><i>Prescription only medicines to which the exemption applies</i>   | <i>Column 3</i><br><i>Conditions</i>   |
|---|--|--|
| 3. Persons selling or supplying prescription only medicines to any person employed or engaged in connection with a scheme for testing the quality and checking the amount of the drugs and appliances supplied under the National Health Service Act 1977(17), the National Health Service (Scotland) Act 1978(18) and the Health and Personal Social Services (Northern Ireland) Order 1972(19), or under any subordinate legislation made under those Acts or that Order. | 3. All prescription only medicines.  | 3. The sale or supply shall be—<br>(a) subject to the presentation of an order signed by or on behalf of the person so employed or engaged stating the status of the person signing it and the amount of prescription only medicine required, and<br>(b) for the purposes of a scheme referred to in column 1 in this paragraph. |
| 4. Registered midwives.   | 4. [F275Prescription only medicines containing any of the following substances—<br>Diclofenac<br>Ergometrine maleate<br>Hydrocortizone Acetate<br>Lidocaine<br>Lidocaine Hydrochloride<br>Miconazole<br>Nystatin<br>Phytomenadione.] | 4. The sale or supply shall be only in the course of their professional practice and in the case of Ergometrine maleate only when contained in a medicinal product which is not for parenteral administration.   |
| 5. Persons lawfully conducting a retail pharmacy business within the meaning of section 69.   | 5. Prescription only medicines which are not for parenteral administration and which—<br>(a) are eyes drops and are prescription only medicines by reason only that they contain not more than                                       | 5. The sale or supply shall be subject to the presentation of an order signed by a [F280registered optometrist].   |

(17) 1977 c. 49.

(18) 1978 c. 29.

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

**Status:** Point in time view as at 17/01/2011.

**Changes to legislation:** There are currently no known outstanding effects for the The Prescription Only Medicines (Human Use) Order 1997. (See end of Document for details)

| <i>Column 1</i><br><i>Persons exempted</i>  | <i>Column 2</i><br><i>Prescription only medicines to which the exemption applies</i>  | <i>Column 3</i><br><i>Conditions</i>   |
|---|---|--|
|   | 0.5 per cent Chloramphenicol, or<br>(b) are eye ointments and are prescription only medicines by reason only that they contain not more than 1.0 per cent Chloramphenicol, or<br>(c) are prescription only medicines by reason only that they contain any of the following substances:<br>F276<br>...<br>F276<br>...<br>F276<br>...<br>Cyclopentolate hydrochloride<br>[ <sup>F277</sup> Fusidic Acid]<br>F278<br>...<br>F278<br>...<br>F278<br>...<br>F278<br>...<br>F279<br>...<br>F278<br>...<br>F278<br>...<br>Tropicamide. |  |
| 6. [ <sup>F281</sup> Registered optometrists]   | 6. Prescription only medicines listed in column 2 of paragraph 5.   | 6. The sale or supply shall be only—<br>(a) in the course of their professional practice and<br>(b) in an emergency. |
| [ <sup>F282</sup> 6A Persons lawfully conducting a retail pharmacy business within the meaning of section 69. | Homotropine hydrobromide<br>Ketotifen<br>Levocabastine<br>Lodoxamide  | The sale or supply shall be subject to the presentation of an order signed by an additional supply optometrist.      |

**Status:** Point in time view as at 17/01/2011.

**Changes to legislation:** There are currently no known outstanding effects for the The Prescription Only Medicines (Human Use) Order 1997. (See end of Document for details)

| <i>Column 1</i>   | <i>Column 2</i>   | <i>Column 3</i>   |
|---|---|---|
| <i>Persons exempted</i>   | <i>Prescription only medicines to which the exemption applies</i>             | <i>Conditions</i>   |
|   | Nedocromil sodium   |   |
|   | Olopatadine   |   |
|   | Pilocarpine hydrochloride   |   |
|   | [ <sup>32</sup> P]Pilocarpine nitrate]  |   |
|   | Polymyxin B/bacitracin  |   |
|   | Polymyxin B/trimethoprim  |   |
|   | Sodium cromoglycate.  |   |
| <b>6B</b> Additional supply optometrists.   | Prescription only medicines specified in column 2 of paragraph 6A.            | The sale or supply shall be only—<br>(a) in the course of their professional practice, and<br>(b) in an emergency.]   |
| 7. Persons selling or supplying prescription only medicines to the British Standards Institution. | 7. All prescription only medicines.   | 7. The sale or supply shall be—<br>(a) subject to the presentation of an order signed on behalf of the British Standards Institution stating the status of the person signing it and the amount of the prescription only medicine required, and<br>(b) only for the purpose of testing containers of medicinal products or determining the standards for such containers. |
| 8. Holders of marketing authorizations, product licences or manufacturer’s licences.              | 8. Prescription only medicines referred to in the authorizations or licences. | 8. The sale or supply shall be only—<br>(a) to a pharmacist,<br>(b) so as to enable that pharmacist to prepare an entry relating to the prescription  |

**Status:** Point in time view as at 17/01/2011.

**Changes to legislation:** There are currently no known outstanding effects for the The Prescription Only Medicines (Human Use) Order 1997. (See end of Document for details)

| <i>Column 1</i><br><i>Persons exempted</i>  | <i>Column 2</i><br><i>Prescription only medicines to which the exemption applies</i>   | <i>Column 3</i><br><i>Conditions</i>   |
|---|--|--|
| <p>9. Pharmacists selling or supplying to persons to whom cyanide salts may be sold by virtue of section 3 (regulation of poisons) or section 4 (exclusion of sales by wholesale and certain other sales) of the Poisons Act 1972(20) or by virtue of article 5 (prohibitions and regulations with respect to sale of poisons) or article 6 (exemption with respect to certain sales) of the Poisons (Northern Ireland) Order 1976(21).</p> | <p>9. Amyl nitrite.</p>  | <p>only medicine in question in a tablet or capsule identification guide or similar publication, and</p> <p>(c) of no greater quantity than is reasonably necessary for that purpose.</p> <p>9. The sale or supply shall only be so far as is necessary to enable an antidote to be available to persons at risk of cyanide poisoning.</p> |
| <p>[<sup>F284</sup>[<sup>F285</sup>10. Registered chiropodists against whose names are recorded in the relevant register annotations signifying that they are qualified to use the medicines specified in column 2.]</p>  | <p>10. The following prescription only medicines—</p> <p>(a) Co-dydramol 10/500 tablets;</p> <p>(b) Amorolfine hydrochloride cream where the maximum strength of the Amorolfine in the cream does not exceed 0.25 per cent by weight in weight;</p> <p>(c) Amorolfine hydrochloride lacquer where the maximum strength of the Amorolfine in the lacquer does not</p> | <p>10. The sale or supply shall be only in the course of their professional practice and (a) in the case of Co-dydramol 10/500 tablets the quantity sold or supplied to a person at any one time shall not exceed the amount sufficient for 3 days' treatment to a maximum of 24 tablets.]</p>   |

(20) 1972 c. 66.

(21) S.I. 1976/1214 (N.I. 23).

**Status:** Point in time view as at 17/01/2011.

**Changes to legislation:** There are currently no known outstanding effects for the The Prescription Only Medicines (Human Use) Order 1997. (See end of Document for details)

| <i>Column 1</i>         | <i>Column 2</i>   | <i>Column 3</i>   |
|-------------------------|---|-------------------|
| <i>Persons exempted</i> | <i>Prescription only medicines to which the exemption applies</i>   | <i>Conditions</i> |
|                         | <p>exceed 5 per cent by weight in volume;<br/> <sup>F286</sup> ...</p> <p>(d) Topical hydrocortisone where the maximum strength of the hydrocortisone in the medicinal product does not exceed 1 per cent by weight [<sup>F287</sup> in weight; and]</p> <p>[ Amoxicillin;<br/> <sup>F288</sup>(e)</p> <p>(f) Erythromycin;<br/>           (g) Flucoxacillin;<br/>           (h) Tioconazole 28%;<br/>           and<br/>           (i) Silver Sulfadiazine.]</p> |                   |

### Textual Amendments

- F275** Words in Sch. 5 Pt. 1 para. 4 substituted (1.6.2010) by The Medicines for Human Use (Miscellaneous Amendments) Order 2010 (S.I. 2010/1136), arts. 1(1), **3(3)(a)**
- F276** Words in Sch. 5 Pt. 1 para. 5 omitted (7.4.2005) by virtue of The Medicines for Human Use (Prescribing) Order 2005 (S.I. 2005/765), arts. 1(1), **8(a)**
- F277** Words in Sch. 5 Pt. 1 para. 5 inserted (7.4.2005) by The Medicines for Human Use (Prescribing) Order 2005 (S.I. 2005/765), arts. 1(1), **8(b)**
- F278** Words in Sch. 5 Pt. 1 omitted (7.4.2005) by virtue of The Medicines for Human Use (Prescribing) Order 2005 (S.I. 2005/765), arts. 1(1), **8(c)**
- F279** Words in Sch. 5 Pt. 1 para. 5 omitted (30.6.2005) by virtue of The Medicines for Human Use (Prescribing) (Miscellaneous Amendments) Order 2005 (S.I. 2005/1507), arts. 1(1), **7(1)(a)**
- F280** Words in Order substituted (30.6.2005 as notified in the London Gazette dated 3.6.2005) by The Opticians Act 1989 (Amendment) Order 2005 (S.I. 2005/848), **Sch. 1 para. 27(b)**
- F281** Words in Order substituted (30.6.2005 as notified in the London Gazette dated 3.6.2005) by The Opticians Act 1989 (Amendment) Order 2005 (S.I. 2005/848), **Sch. 1 para. 27(b)**
- F282** Sch. 5 Pt. 1 paras. 6A, 6B inserted (30.6.2005) by The Medicines for Human Use (Prescribing) (Miscellaneous Amendments) Order 2005 (S.I. 2005/1507), arts. 1(1), **7(1)(b)**
- F283** Words in Sch. 5 Pt. 1 Table inserted (6.1.2006) by The Medicines for Human Use (Prescribing) (Miscellaneous Amendments) (No. 2) Order 2005 (S.I. 2005/3324), arts. 1(1), **3**
- F284** Words in Sch. 5 Pt. 1 para. 10 substituted (17.11.2006) by The Medicines for Human Use (Administration and Sale or Supply) (Miscellaneous Amendments) Order 2006 (S.I. 2006/2807), arts. 1(1), **4(2)(a)**
- F285** Sch. 5 Pt. 1 para. 10 inserted (13.2.1998) by The Prescription Only Medicines (Human Use) Amendment Order 1998 (S.I. 1998/108), art. 1, **Sch.**

- F286** Word in Sch. 5 Pt. 1 para. 10 omitted (17.11.2006) by virtue of The Medicines for Human Use (Administration and Sale or Supply) (Miscellaneous Amendments) Order 2006 (S.I. 2006/2807), arts. 1(1), **4(2)(b)(i)**
- F287** Words in Sch. 5 Pt. 1 para. 10 substituted (17.11.2006) by The Medicines for Human Use (Administration and Sale or Supply) (Miscellaneous Amendments) Order 2006 (S.I. 2006/2807), arts. 1(1), **4(2)(b)(ii)**
- F288** Words in Sch. 5 Pt. 1 para. 10 added (17.11.2006) by The Medicines for Human Use (Administration and Sale or Supply) (Miscellaneous Amendments) Order 2006 (S.I. 2006/2807), arts. 1(1), **4(2)(b)(iii)**

Article 11(1)(b)

## PART II

## EXEMPTIONS FROM THE RESTRICTION ON SUPPLY

| <i>Column 1</i><br><i>Persons exempted</i>  | <i>Column 2</i><br><i>Prescription only medicines to which the exemption applies</i>          | <i>Column 3</i><br><i>Conditions</i>   |
|---|---|--|
| 1. Royal National Lifeboat Institution and certified first aiders of the Institution.   | 1. All prescription only medicines.   | 1. The supply shall be only so far as is necessary for the the treatment of sick or injured persons in the exercise of the functions of the Institution.   |
| 2. The owner or the master of a ship which does not carry a doctor on board as part of her complement.  | 2. All prescription only medicines.   | 2. The supply shall be only so far as is necessary for the treatment of persons on the ship.   |
| 3. Persons authorized by licences granted under regulation 5 of the Misuse of Drugs Regulations to supply a controlled drug.  | 3. Such prescription only medicines, being controlled drugs, as are specified in the licence. | 3. The supply shall be subject to such conditions and in such circumstances and to such an extent as may be specified in the licence.  |
| [ <sup>F289</sup> 3A. Persons employed or engaged in the provision of lawful drug treatment services.   | 3A. Ampoules of sterile water for injection containing not more than 2 ml of sterile water.   | 3A. The supply shall be only in the course of provision of lawful drug treatment services.]  |
| 4. Persons requiring prescription only medicines for the purpose of enabling them, in the course of any business carried on by them, to comply with any requirements made by or in pursuance of any enactment with respect to the medical treatment of their employees. | 4. Such prescription only medicines as may be specified in the relevant enactment.            | 4. The supply shall be—<br>(a) for the purpose of enabling them to comply with any requirements made by or in pursuance of any such enactment, and<br>(b) subject to such conditions and in such circumstances as may be specified |

**Status:** Point in time view as at 17/01/2011.

**Changes to legislation:** There are currently no known outstanding effects for the The Prescription Only Medicines (Human Use) Order 1997. (See end of Document for details)

| <i>Column 1</i><br><i>Persons exempted</i>  | <i>Column 2</i><br><i>Prescription only medicines to which the exemption applies</i>  | <i>Column 3</i><br><i>Conditions</i>  |
|---|---|---|
|   |   | in the relevant enactment.  |
| 5. Persons operating an occupational health scheme.   | 5. Prescription only medicines sold or supplied to a person operating an occupational health scheme in response to an order in writing signed by a doctor or a registered nurse.                                    | 5. —<br>(1) The supply shall be in the course of an occupational health scheme.<br>(2) The individual supplying the prescription only medicine, if not a doctor, shall be a registered nurse acting in accordance with the written instructions of a doctor as to the circumstances in which prescription only medicines of the description in question are to be used in the course of the occupational health scheme. |
| 6. The operator or commander of an aircraft.  | 6. Prescription only medicines which are not for parenteral administration and which have been sold or supplied to the operator or commander of the aircraft in response to an order in writing signed by a doctor. | 6. The supply shall be only so far as is necessary for the immediate treatment of sick or injured persons on the aircraft and shall be in accordance with the written instructions of a doctor as to the circumstances in which prescription only medicines of the description in question are to be used on the aircraft.  |
| 7. Persons employed as qualified first-aid personnel on offshore installations.   | 7. All prescription only medicines.   | 7. The supply shall be only so far as is necessary for the treatment of persons on the installation.  |
| [ <sup>F290</sup> 8. Persons who hold a certificate in first aid from the Mountain Rescue Council of England and Wales, or from the Northern Ireland Mountain | 8 Prescription only medicines supplied to a person specified in column 1 in response to an order in writing signed by a doctor.   | 8 The supply shall be only so far as is necessary for the treatment of sick or injured persons in the course of providing mountain rescue services.]  |



| <i>Column 1</i>  | <i>Column 2</i>   | <i>Column 3</i>   |
|--|---|---|
| <i>Persons exempted</i>  | <i>Prescription only medicines to which the exemption applies</i> | <i>Conditions</i>   |
| Rescue Co-ordinating Committee.<br><br>[ <sup>F291</sup> 9. Persons (“P”) who are members of Her Majesty’s armed forces. | 9. All prescription only medicines.                               | 9. The supply shall be—<br>(a) in the course of P undertaking any function as a member of Her Majesty’s armed forces; and<br>(b) where P is satisfied that it is not practicable for another person who is legally entitled to supply a prescription only medicine to do so; and<br>(c) only in so far as is necessary—<br>(i) for the treatment of a sick or injured person in a medical emergency, or<br>(ii) to prevent ill-health where there is a risk that a person would suffer ill-health if the prescription only medicine is not supplied.] |

**Textual Amendments**

**F289** Sch. 5 Pt. 2 para. 3A inserted (30.6.2005) by The Medicines for Human Use (Prescribing) (Miscellaneous Amendments) Order 2005 (S.I. 2005/1507), arts. 1(1), **7(2)**

**F290** Sch. 5 Pt. 2 para. 8 inserted (17.11.2006) by The Medicines for Human Use (Administration and Sale or Supply) (Miscellaneous Amendments) Order 2006 (S.I. 2006/2807), arts. 1(1), **4(3)**

**F291** Sch. 5 Pt. 3 para. 10 added (21.12.2009) by The Medicines (Exemptions and Miscellaneous Amendments) Order 2009 (S.I. 2009/3062), arts. 1(1), **3(2)**

Article 11(2)

**Status:** Point in time view as at 17/01/2011.

**Changes to legislation:** There are currently no known outstanding effects for the The Prescription Only Medicines (Human Use) Order 1997. (See end of Document for details)

### PART III

#### EXEMPTIONS FROM RESTRICTION ON ADMINISTRATION Column 1

| <i>Column 1<br/>Persons exempted</i>   | <i>Column 2<br/>Prescription only medicines<br/>to which the exemption<br/>applies</i>  | <i>Column 3<br/>Conditions</i>   |
|--|---|--|
| <p>[<sup>F292</sup>1. Registered chiropodists against whose names are recorded in the relevant register annotations signifying that they are qualified to use the medicines specified in column 2..]</p> | <p>1. Prescription only medicines for parenteral administration that contain, as the sole active ingredient, not more than one of the following substances—</p> <ul style="list-style-type: none"> <li>[<sup>F293</sup>Adrenaline]</li> <li>[<sup>F294</sup>Bupivacaine hydrochloride<br/>Bupivacaine hydrochloride with adrenaline where the maximum strength of the adrenaline does not exceed 1 mg in 200 ml of bupivacaine hydrochloride</li> <li>[<sup>F293</sup>Levobupivacaine hydrochloride]</li> <li>Lignocaine hydrochloride<br/>Lignocaine hydrochloride with adrenaline where the maximum strength of the adrenaline does not exceed 1 mg in 200 ml of lignocaine hydrochloride</li> <li>[<sup>F295</sup>Mepivacaine hydrochloride]</li> <li>[<sup>F293</sup>Methylprednisolone]</li> <li>Prilocaine hydrochloride.]</li> <li>[<sup>F293</sup>Ropivacaine hydrochloride]</li> </ul> | <p>1. The administration shall be only in the course of their professional practice.</p>                             |
| <p>2. Registered midwives.</p>   | <p>2. Prescription only medicines for parenteral administration containing any of the following</p>   | <p>2. The administration shall be only in the course of their professional practice and in the case of Promazine</p> |

**Status:** Point in time view as at 17/01/2011.

**Changes to legislation:** There are currently no known outstanding effects for the The Prescription Only Medicines (Human Use) Order 1997. (See end of Document for details)

| <i>Column 1</i><br><i>Persons exempted</i>  | <i>Column 2</i><br><i>Prescription only medicines to which the exemption applies</i>  | <i>Column 3</i><br><i>Conditions</i>   |
|---|---|--|
|   | substances but no other substance specified in column 1 of Schedule 1 to this Order—<br>[ <sup>296</sup> F Adrenaline<br>Anti-D immunoglobulin<br>Carboprost<br>Cyclizine hydrochloride<br>Diamorphine<br>Ergometrine maleate<br>Gelofusine<br>Haemaccel<br>Hartmann’s solution<br>Hepatitis B vaccine<br>Hepatitis immunoglobulin<br>Lidocaine<br>Lidocaine hydrochloride<br>Morphine<br>Naloxone hydrochloride<br>Oxytocins, natural and synthetic<br>Pethidine hydrochloride<br>Phytomenadione<br>Prochlorperazine<br>Sodium chloride 0.9%.] | hydrochloride, Lignocaine and Lignocaine hydrochloride shall be only while attending on a woman in childbirth.                                     |
| 3. Persons who are authorized as members of a group by a group authority granted under regulations 8(3) or 9(3) of the Misuse of Drugs Regulations to supply a controlled drug by way of administration only. | 3. Prescription only medicines that are specified in the group authority.   | 3. The administration shall be subject to such conditions and in such circumstances and to such extent as may be specified in the group authority. |
| 4. The owner or master of a ship which does not carry a doctor on board as part of her complement.  | 4. All prescription only medicines that are for parenteral administration.  | 4. The administration shall be only so far as is necessary for the treatment of persons on the ship.   |
| 5. Persons operating an occupational health scheme.   | 5. Prescription only medicines for parenteral administration  | 5. —   |

**Status:** Point in time view as at 17/01/2011.

**Changes to legislation:** There are currently no known outstanding effects for the The Prescription Only Medicines (Human Use) Order 1997. (See end of Document for details)

| <i>Column 1</i><br><i>Persons exempted</i>  | <i>Column 2</i><br><i>Prescription only medicines to which the exemption applies</i>  | <i>Column 3</i><br><i>Conditions</i>   |
|---|---|--|
|   | sold or supplied to the person operating an occupational health scheme in response to an order in writing signed by a doctor or a registered nurse.   | (1) The administration shall be in the course of an occupational health scheme.<br>(2) The individual administering the prescription only medicine, if neither a doctor nor acting in accordance with the directions of a doctor, shall be a registered nurse acting in accordance with the written instructions of a doctor as to the circumstances in which prescription only medicines of the description in question are to be used in the course of the occupational health scheme. |
| 6. The operator or commander of an aircraft.  | 6. Prescription only medicines for parenteral administration which have been sold or supplied to the operator or commander of the aircraft in response to an order in writing signed by a doctor. | 6. The administration shall be only so far as is necessary for the immediate treatment of sick or injured persons on the aircraft and shall be in accordance with the written instructions of a doctor as to the circumstances in which prescription only medicines of the description in question are to be used on the aircraft.   |
| 7. Persons who are, and at 11th February 1982 were, persons customarily administering medicinal products to human beings by parenteral administration in the course of a business in the field of osteopathy, naturopathy, acupuncture or other similar field except chiropody. | 7. Medicinal products that are prescription only medicines by reason only that they fall within the class specified in article 3(c) (products for parenteral administration).                     | 7. The person administering the prescription only medicine shall have been requested by or on behalf of the person to whom it is administered and in that person's presence to use his own judgement as to the treatment required.   |

**Status:** Point in time view as at 17/01/2011.

**Changes to legislation:** There are currently no known outstanding effects for the The Prescription Only Medicines (Human Use) Order 1997. (See end of Document for details)

| <i>Column 1</i><br><i>Persons exempted</i>  | <i>Column 2</i><br><i>Prescription only medicines to which the exemption applies</i>   | <i>Column 3</i><br><i>Conditions</i>   |
|---|--|--|
| 8. Persons employed as qualified first-aid personnel on offshore installations.   | 8. All prescription only medicines that are for parenteral administration.   | 8. The administration shall be only so far as is necessary for the treatment of persons on the installation.   |
| 9. Persons who hold a certificate of proficiency in ambulance paramedic skills issued by, or with the approval of, the Secretary of State [ <sup>F297</sup> or persons who are [ <sup>F298</sup> registered] paramedics]. | 9. The following prescription only medicines for parenteral administration—<br>(a) Diazepam 5 mg per ml emulsion for injection;<br>(b) Succinylated Modified Fluid Gelatin 4 per cent intravenous infusion;<br>(bb) [ <sup>F299</sup> medicines containing the substances Ergometrine Maleate 500mcg per ml with Oxytocin 5 iu per ml, but no other active ingredient]<br>(d) prescription only medicines containing one or more of the following substances, but no active ingredient—<br>Adrenaline<br>Acid Tartrate<br>[ <sup>F300</sup> Adrenaline Hydrochloride]<br>[ <sup>F301</sup> Amiodarone] Anhydrous<br>Glucose<br>[ <sup>F302</sup> Benzylpenicillin]<br>[ <sup>F303</sup> Bretylium Tosylate] Compound<br>Sodium<br>Lactate<br>Intravenous<br>Infusion | 9. The administration shall be only for the immediate, necessary treatment of sick or injured persons and in the case of a prescription only medicine containing Heparin Sodium shall be only for the purpose of cannula flushing. |

**Status:** Point in time view as at 17/01/2011.

**Changes to legislation:** There are currently no known outstanding effects for the The Prescription Only Medicines (Human Use) Order 1997. (See end of Document for details)

| <i>Column 1</i><br><i>Persons exempted</i>   | <i>Column 2</i><br><i>Prescription only medicines to which the exemption applies</i>   | <i>Column 3</i><br><i>Conditions</i>   |
|--|--|--|
|  | (Hartmann's Solution)<br>Ergometrine Maleate<br>[ <sup>F302</sup> Frusemide]<br>Glucose<br>Heparin Sodium<br>Lignocaine Hydrochloride<br>[ <sup>F302</sup> Metoclopramide]<br>[ <sup>F302</sup> Morphine Sulphate]<br>Nalbuphine Hydrochloride<br>Naloxone Hydrochloride<br>Polygeline<br>[ <sup>F304</sup> Reteplase]<br> <br>Sodium Bicarbonate<br>Sodium Chloride<br>[ <sup>F302</sup> Streptokinase]<br>[ <sup>F304</sup> Tenecteplase.] | 10. The administration shall be—<br>(a) in the course of P undertaking any function as a member of Her Majesty's armed forces; and<br>(b) where P is satisfied that it is not practicable for another person who is legally entitled to administer a prescription only medicine to do so; and<br>(c) only in so far as is necessary—<br>(i) for the treatment of a sick or injured person in a medical emergency, or |
| [ <sup>F291</sup> 10. Persons ("P") who are members of Her Majesty's armed forces. | 10. All prescription only medicines.   |  |

**Status:** Point in time view as at 17/01/2011.**Changes to legislation:** There are currently no known outstanding effects for the The Prescription Only Medicines (Human Use) Order 1997. (See end of Document for details)

| <i>Column 1</i>         | <i>Column 2</i>   | <i>Column 3</i>  |
|-------------------------|---|--|
| <i>Persons exempted</i> | <i>Prescription only medicines to which the exemption applies</i> | (ii) to prevent ill-health where there is a risk that a person would suffer ill-health if the prescription only medicine is not administered.] |

**Textual Amendments**

- F292** Words in Sch. 5 Pt. 3 para. 1 substituted (17.11.2006) by The Medicines for Human Use (Administration and Sale or Supply) (Miscellaneous Amendments) Order 2006 (S.I. 2006/2807), arts. 1(1), **4(4)(a)**
- F293** Words in Sch. 5 Pt. 3 para. 1 inserted (17.11.2006) by The Medicines for Human Use (Administration and Sale or Supply) (Miscellaneous Amendments) Order 2006 (S.I. 2006/2807), arts. 1(1), **4(4)(b)**
- F294** Words in Sch. 5 Pt. 3 substituted (13.2.1998) by The Prescription Only Medicines (Human Use) Amendment Order 1998 (S.I. 1998/108), arts. 1, **5(2)**
- F295** Words in Sch. 5 Pt. 3 para. 1 inserted (16.9.1998) by The Prescription Only Medicines (Human Use) Amendment (No. 3) Order 1998 (S.I. 1998/2081), arts. 1(1), **4(b)**
- F296** Words in Sch. 5 Pt. 3 para. 2 substituted (1.6.2010) by The Medicines for Human Use (Miscellaneous Amendments) Order 2010 (S.I. 2010/1136), arts. 1(1), **3(3)(b)**
- F297** Words in Sch. 5 Pt. 3 para. 9 added (16.11.2000) by The Prescription Only Medicines (Human Use) Amendment (No. 2) Order 2000 (S.I. 2000/2899), arts. 1(1), **5(a)**
- F298** Word in Sch. 5 Pt. 3 para. 9 substituted for words (9.7.2003) by The Health Professions Order 2001 (Consequential Amendments) Order 2003 (S.I. 2003/1590), art. 1, **Sch. para. 21(3)(b)(ii)**
- F299** Words in Sch. 5 Pt. 3 para. 9 inserted (16.11.2000) by The Prescription Only Medicines (Human Use) Amendment (No. 2) Order 2000 (S.I. 2000/2899), arts. 1(1), **5(b)**
- F300** Words in Sch. 5 Pt. 3 para. 9 added (17.1.2011) by The Prescription Only Medicines (Human Use) Amendment Order 2010 (S.I. 2010/2998), arts. 1(1), **3**
- F301** Word in Sch. 5 Pt. 3 para. 9 inserted (19.11.2004) by The Prescription Only Medicines (Human Use) Amendment (No. 3) Order 2004 (S.I. 2004/2693), arts. 1(1), **6**
- F302** Words in Sch. 5 Pt. 3 para. 9 inserted (16.11.2000) by The Prescription Only Medicines (Human Use) Amendment (No. 2) Order 2000 (S.I. 2000/2899), arts. 1(1), **5(c)**
- F303** Words in Sch. 5 Pt. 3 para. 9 inserted (1.6.1998) by The Prescription Only Medicines (Human Use) Amendment (No. 2) Order 1998 (S.I. 1998/1178), arts. 1(1), **3**
- F304** Words in Sch. 5 Pt. 3 para. 9 inserted (18.5.2004) by The Prescription Only Medicines (Human Use) Amendment (No. 2) Order 2004 (S.I. 2004/1189), arts. 1(1), **4**

*Status: Point in time view as at 17/01/2011.**Changes to legislation: There are currently no known outstanding effects for the The Prescription Only Medicines (Human Use) Order 1997. (See end of Document for details)*

## SCHEDULE 6

Article 16(1)

## ORDERS REVOKED

| <i>Column 1</i><br><i>Orders</i>  | <i>Column 2</i><br><i>References</i> |
|---|--------------------------------------|
| The Medicines (Products other than Veterinary Drugs) (Prescription Only) Order 1983                   | <a href="#">S.I. 1983/1212</a>       |
| The Medicines (Products other than Veterinary Drugs) (Prescription Only) Amendment Order 1984         | <a href="#">S.I. 1984/756</a>        |
| The Medicines (Products other than Veterinary Drugs) (Prescription Only) Amendment Order 1986         | <a href="#">S.I. 1986/586</a>        |
| The Medicines (Products other than Veterinary Drugs) (Prescription Only) Amendment Order 1987         | <a href="#">S.I. 1987/674</a>        |
| The Medicines (Products other than Veterinary Drugs) (Prescription Only) Amendment (No. 2) Order 1987 | <a href="#">S.I. 1987/1250</a>       |
| The Medicines (Products other than Veterinary Drugs) (Prescription Only) Amendment Order 1988         | <a href="#">S.I. 1988/2017</a>       |
| The Medicines (Products other than Veterinary Drugs) (Prescription Only) Amendment Order 1991         | <a href="#">S.I. 1991/962</a>        |
| The Medicines (Products other than Veterinary Drugs) (Prescription Only) Amendment Order 1992         | <a href="#">S.I. 1992/1534</a>       |
| The Medicines (Products other than Veterinary Drugs) (Prescription Only) Amendment (No. 2) Order 1992 | <a href="#">S.I. 1992/2937</a>       |
| The Medicines (Products other than Veterinary Drugs) (Prescription Only) Amendment Order 1993         | <a href="#">S.I. 1993/1890</a>       |
| The Medicines (Products other than Veterinary Drugs) (Prescription Only) Amendment (No. 2) Order 1993 | <a href="#">S.I. 1993/3256</a>       |
| The Medicines (Products other than Veterinary Drugs) (Prescription Only) Amendment Order 1994         | <a href="#">S.I. 1994/558</a>        |
| The Medicines (Products other than Veterinary Drugs) (Prescription Only) Amendment (No. 2) Order 1994 | <a href="#">S.I. 1994/3016</a>       |



| <i>Column 1</i><br><i>Orders</i>  | <i>Column 2</i><br><i>References</i> |
|---|--------------------------------------|
| The Medicines (Products other than Veterinary Drugs) (Prescription Only) Amendment (No. 3) Order 1994 | <a href="#">S.I. 1994/3050</a>       |
| The Medicines (Products other than Veterinary Drugs) (Prescription Only) Amendment Order 1995         | <a href="#">S.I. 1995/1384</a>       |
| The Medicines (Products other than Veterinary Drugs) (Prescription Only) Amendment (No. 2) Order 1995 | <a href="#">S.I. 1995/3174</a>       |
| The Medicines (Products other than Veterinary Drugs) (Prescription Only) Amendment Order 1996         | <a href="#">S.I. 1996/1514</a>       |
| The Medicines (Products other than Veterinary Drugs) (Prescription Only) Amendment (No. 2) Order 1996 | <a href="#">S.I. 1996/3193</a>       |

[<sup>F305</sup>SCHEDULE 7

Articles 12A to 12C

**Textual Amendments**

**F305** Sch. 7 inserted (9.8.2000) by The Prescription Only Medicines (Human Use) Amendment Order 2000 (S.I. 2000/1917), arts. 1(1), 2(e)

**PART I****PARTICULARS TO BE INCLUDED IN A PATIENT GROUP DIRECTION**

- (a) the period during which the Direction shall have effect;
- (b) the description or class of prescription only medicine to which the Direction relates;
- (c) whether there are any restrictions on the quantity of medicine which may be [<sup>F306</sup>sold or] supplied on any one occasion, and, if so, what restrictions;
- (d) the clinical situations which prescription only medicines of that description or class may be used to treat;
- (e) the clinical criteria under which a person shall be eligible for treatment;
- (f) whether any class of person is excluded from treatment under the Direction and, if so, what class of person;
- (g) whether there are circumstances in which further advice should be sought from a doctor or dentist and, if so, what circumstances;
- (h) the pharmaceutical form or forms in which prescription only medicines of that description or class are to be administered;

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- (i) the strength, or maximum strength, at which prescription only medicines of that description or class are to be administered;
- (j) the applicable dosage or maximum dosage;
- (k) the route of administration;
- (l) the frequency of administration;
- (m) any minimum or maximum period of administration applicable to prescription only medicines of that description or class;
- (n) whether there are any relevant warnings to note, and, if so, what warnings;
- (o) whether there is any follow up action to be taken in any circumstances, and, if so, what action and in what circumstances;
- (p) arrangements for referral for medical advice;
- (q) details of the records to be kept of the supply, or the administration, of medicines under the Direction.

**Textual Amendments**

**F306** Words in Sch. 7 Pt. 1 inserted (1.9.2007) by The Medicines for Human Use (Administration and Sale or Supply) (Miscellaneous Amendments) Order 2007 (S.I. 2007/2178), arts. 1(1), 5

**PART II**

**PERSONS ON WHOSE BEHALF A PATIENT GROUP DIRECTION MUST BE SIGNED**

| <b>Column 1</b>   | <b>Column 2</b>   |
|---|---|
| Class of person by whom a prescription only medicine is supplied or administered  | Person on whose behalf the Direction must be signed   |
| Common Services Agency  | The Agency  |
| [ <sup>F307</sup> Strategic Health Authority]   | [ <sup>F307</sup> The Strategic Health Authority]   |
| Health Authority  | The Health Authority  |
| Special Health Authority  | The Special Health Authority  |
| NHS trust [ <sup>F308</sup> or NHS foundation trust]  | The trust   |
| Primary Care Trust  | The Trust   |
| A person who supplies or administers a prescription only medicine pursuant to an arrangement made with the Common Services Agency, a Health Authority, a Special Health Authority, an NHS trust, [ <sup>F309</sup> an NHS foundation trust] or a Primary Care Trust | The Common Services Agency, where the arrangement has been made with the Agency; or the Health Authority, Special Health Authority, NHS trust [ <sup>F310</sup> or NHS foundation trust] or Primary Care Trust with which the arrangement has been made |

**Textual Amendments**

- F307** Words in Sch. 7 Pt. 2 inserted (1.10.2002) by The National Health Service Reform and Health Care Professions Act 2002 (Supplementary, Consequential etc. Provisions) Regulations 2002 (S.I. 2002/2469), reg. 1, **Sch. 1 para. 73(4)**
- F308** Words in Sch. 7 Pt. 2 inserted (1.4.2004) by The Health and Social Care (Community Health and Standards) Act 2003 (Supplementary and Consequential Provision) (NHS Foundation Trusts) Order 2004 (S.I. 2004/696), arts. 1(1)(b), 3(2), **Sch. 2**
- F309** Words in Sch. 7 Pt. 2 inserted (1.4.2004) by The Health and Social Care (Community Health and Standards) Act 2003 (Supplementary and Consequential Provision) (NHS Foundation Trusts) Order 2004 (S.I. 2004/696), arts. 1(1)(b), 3(4), **Sch. 4**
- F310** Words in Sch. 7 Pt. 2 inserted (1.4.2004) by The Health and Social Care (Community Health and Standards) Act 2003 (Supplementary and Consequential Provision) (NHS Foundation Trusts) Order 2004 (S.I. 2004/696), arts. 1(1)(b), 3(3), **Sch. 3**

**[<sup>F311</sup>PART IIA**

**PERSONS BY WHOM OR ON WHOSE BEHALF A PATIENT  
GROUP DIRECTION USED IN THE PROVISION OF HEALTH  
CARE BY OR ON BEHALF OF THE POLICE, THE PRISON  
SERVICES OR THE ARMED FORCES MUST BE SIGNED**

**Textual Amendments**

- F311** Sch. 7 Pt. 2A inserted (4.4.2003) by The Prescription Only Medicines (Human Use) Amendment Order 2003 (S.I. 2003/696), arts. 1(1), **17**

| <i>Column 1</i>  | <i>Column 2</i>   |
|--|---|
| <b>Force or service by whom or on whose behalf the health care is provided</b> | <b>Person by whom or on whose behalf the Direction must be signed</b>                           |
| A police force in England or Wales   | The chief officer of police for that police force (within the meaning of the Police Act 1996)   |
| A police force in Scotland   | The chief constable of that police force (within the meaning of the Police (Scotland) Act 1997) |
| The Police Service of Northern Ireland   | The Chief Constable of the Police Service of Northern Ireland                                   |
| The prison service in England and Wales  | The governor of the prison in relation to which the health care in question is being provided   |
| The prison service in Scotland   | The Scottish Prison Service Management Board  |
| The prison service in Northern Ireland   | The Northern Ireland Prison Service Management Board  |
| Her Majesty's Forces   | (i) the Surgeon General,<br>(ii) a Medical Director General, or                                 |

*Status: Point in time view as at 17/01/2011.*

*Changes to legislation: There are currently no known outstanding effects for the The Prescription Only Medicines (Human Use) Order 1997. (See end of Document for details)*

| <i>Column 1</i>  | <i>Column 2</i>  |
|--|--|
| <b>Force or service by whom or on whose behalf the health care is provided</b> | <b>Person by whom or on whose behalf the Direction must be signed</b>      |
|  | (iii) a chief executive of an executive agency of the Ministry of Defence] |

## PART III

### CLASSES OF INDIVIDUAL [<sup>F312</sup>BY WHOM PRESCRIPTION ONLY MEDICINES MAY BE SUPPLIED OR ADMINISTERED]

#### Textual Amendments

**F312** Words in Sch. 7 Pt. 3 heading substituted (16.11.2000) by [The Prescription Only Medicines \(Human Use\) Amendment \(No. 2\) Order 2000 \(S.I. 2000/2899\)](#), arts. 1(1), **3(2)**

[<sup>F313</sup>Dental hygienist.

Dental therapist.]

[<sup>F314</sup>Registered paramedics or individuals who hold a certificate of proficiency in ambulance paramedic skills issued by, or with the approval of, the Secretary of State.]

Pharmacists.

<sup>F315</sup> ...

Registered midwives.

Registered nurses.

[<sup>F316</sup>Registered optometrists]

[<sup>F317</sup>Registered] chiropodists.

[<sup>F318</sup>Registered orthoptists.

Registered physiotherapists.

Registered radiographers.]

[<sup>F319</sup>“Registered dietitians.”;]

[<sup>F319</sup>“Registered occupational therapists.”;]

[<sup>F319</sup>“Registered orthotists and prosthetists.”; and]

[<sup>F319</sup>“Registered speech and language therapists.”]]

#### Textual Amendments

**F313** Words in Sch. 7 Pt. 3 inserted (1.6.2010) by [The Medicines for Human Use \(Miscellaneous Amendments\) Order 2010 \(S.I. 2010/1136\)](#), arts. 1(1), **3(4)**

**F314** Words in Sch. 7 Pt. 3 substituted (9.7.2003) by [The Health Professions Order 2001 \(Consequential Amendments\) Order 2003 \(S.I. 2003/1590\)](#), art. 1, **Sch. para. 21(4)(a)**

**F315** Words in Sch. 7 Pt. 3 omitted (1.8.2004) by virtue of [The Health Act 1999 \(Consequential Amendments\) \(Nursing and Midwifery\) Order 2004 \(S.I. 2004/1771\)](#), art. 1(1), **Sch. para. 39(b)**

- F316** Words in Order substituted (30.6.2005 as notified in the London Gazette dated 3.6.2005) by The Opticians Act 1989 (Amendment) Order 2005 (S.I. 2005/848), **Sch. 1 para. 27(b)**
- F317** Word in Sch. 7 Pt. 3 substituted (9.7.2003) by The Health Professions Order 2001 (Consequential Amendments) Order 2003 (S.I. 2003/1590), art. 1, **Sch. para. 21(4)(b)**
- F318** Words in Sch. 7 Pt. 3 substituted (9.7.2003) by The Health Professions Order 2001 (Consequential Amendments) Order 2003 (S.I. 2003/1590), art. 1, **Sch. para. 21(4)(c)**
- F319** Words in Sch. 7 Pt. 3 added (18.5.2004) by The Prescription Only Medicines (Human Use) Amendment (No. 2) Order 2004 (S.I. 2004/1189), arts. 1(1), 5

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## EXPLANATORY NOTE

*(This note is not part of the Order)*

This Order consolidates with amendments the Medicines (Products Other Than Veterinary Drugs) (Prescription Only) Order 1983 as amended. That Order and the Orders amending it (“the 1983 Order as amended”) are revoked by article 16 and Schedule 6.

This Order specifies the descriptions and classes of prescription only medicines (i.e. medicinal products which, subject to exemptions, may be sold or supplied by retail only in accordance with a prescription given by an appropriate practitioner and which may be administered only by or in accordance with the directions of such a practitioner). Many medicinal products are included in a class of such medicines by reason of the substances contained in them (*see* Schedule 1) but others are included because of other criteria, such as their method of administration (*see* article 3). In many cases the provisions of the Act apply subject to exemptions (*see* articles 4 and 5 to 13 and Schedule 1).

The principal amendments relate to those medicines in respect of which marketing authorizations have been granted by the European Community. They include as prescription only medicines those medicines in respect of which such an authorization has been granted which classifies a medicine as being subject to medical prescription (article 3(f)). They exclude from the class of prescription only medicines those medicines in respect of which such an authorization provides for supply which is not subject to medical prescription (article 6(3)).

The differences between this Order and the 1983 Order as amended are in the main technical changes concerning the location of provisions such as the division of material in Schedule 1 to the 1983 Order as amended between the new Schedules 1 and 2. But within the new Schedule 1 there are changes which relate to—

- (a) the deletion from Column 1 of substances which are no longer used in those medicinal products which are on the market;
- (b) the use of current names for the substances which are specified in that Column where their names have changed;
- (c) the incorporation in that Schedule of provisions from article 4 of, and Part IV of Schedule 1 to, the 1983 Order as amended so that they may be found more easily;
- (d) a change in the legal base for the entries in Columns 2 to 4 so that those entries now form the criteria for exemptions from the sale or supply requirements of section 58(2) of the Medicines Act 1968 instead of the criteria for excluding medicinal products from the class of prescription only medicines (*see also* article 5);

**Status:** Point in time view as at 17/01/2011.

**Changes to legislation:** There are currently no known outstanding effects for the The Prescription Only Medicines (Human Use) Order 1997. (See end of Document for details)

- (e) the introduction of a fifth Column which specifies the maximum pack sizes to which exemptions apply.

As this order will impose no additional costs to business a compliance cost assessment has not been prepared.

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**Changes to legislation:**

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