

**EXPLANATORY MEMORANDUM TO THE
THE PRESCRIPTION ONLY MEDICINES (HUMAN USE) AMENDMENT
(No. 3) ORDER 2004**

2004 No. 2693

1. This explanatory memorandum has been prepared by the Department of Health and is laid before Parliament by Command of Her Majesty.

2. **Description**
 - 2.1 This Order amends the Prescription Only Medicines (Human Use) Order 1997 (“the principal Order”) which specifies the description and classes of medicines (“prescription only medicines”) which, subject to exemptions specified in the Order, may be sold or supplied only in accordance with the prescription of an “appropriate practitioner”, and may be administered only in accordance with the directions of such a practitioner.

3. **Matters of special interest to the Joint Committee on Statutory Instruments**
 - 3.1 None

4. **Legislative Background**
 - 4.1 This Order amends the Prescription Only Medicines (Human Use) Order 1997 ("the principal Order"), which specifies the descriptions and classes of medicines ("prescription only medicines") which, subject to exemptions specified in the Order, may be sold or supplied only in accordance with the prescription of an "appropriate practitioner", and may be administered only in accordance with the directions of such a practitioner (see section 58(2) of the Medicines Act 1968).

Article 2 amends article 7 of the principal Order so as to extend the exemption for administration for the purposes of saving life in an emergency to the following medicinal products—

Atropine sulphate and obidoxime chloride injection

Atropine sulphate and pralidoxime chloride injection

Atropine sulphate, pralidoxime mesilate and avizafone injection

Pralidoxime chloride injection

Pralidoxime mesilate injection.

Article 3 inserts a new article 7A of the principal Order so as to create an exemption where smallpox vaccine is administered for the purposes of providing protection either in the event of a confirmed or suspected case of smallpox, or where the vaccine is administered by Her Majesty’s Forces.

Article 4 amends Schedule 3A to the principal Order so as to provide that certain substances may be prescribed or administered by an extended

formulary nurse prescriber only if administered in the course of providing palliative care.

Article 5 amends Part III of Schedule 5 of the principal Order so as to add amiodarone to the list of substances that may be parenterally administered by paramedics for the immediate, necessary treatment of sick or injured persons.

5. **Extent**

5.1 This instrument applies to all of the United Kingdom

6. **European Convention on Human Rights**

The Lord Warner has made the following statement under section 19(1)(a) of the Human Rights Act 1998:

“In my view the provisions of the Prescription Only Medicines (Human Use) Amendment (No.3) Order 2004 are compatible with the Convention rights”

7. **Policy background**

7.1 This Order ensures that, in emergencies arising from poisoning by organophosphate pesticides and nerve agents or emergencies occasioned by a confirmed or suspected case of smallpox, appropriate medication can be administered as quickly as possible by a range of health professionals, and others, without the need for individual prescriptions. This is an integral part of the UK's contingency plans to deal with such emergencies. The Order also clarifies that certain substances may be prescribed or administered by an extended formulary nurse prescriber only if administered in the course of providing palliative care and it also extends the range of substances that may be parenterally administered by paramedics for the immediate, necessary treatment of sick or injured persons. These form part of the Government's policy of enabling appropriately trained healthcare professionals to prescribe, supply and administer medicines in the interests of improving patient care by appropriate use of professional skills. The proposals were subject to public consultation and advice to Ministers by the Committee on Safety of Medicines.

8. **Impact**

8.1 No Regulatory Impact Assessment was prepared in respect of the extension of the substances that can be administered by paramedics as there was no impact on business charities or voluntary bodies. Nor, for the same reason, was a Regulatory Impact Assessment prepared for the clarifications in respect of extended formulary nurse prescribers. The Regulatory Impact Assessment for the extension of Article 7 of the principal Order is attached. This sets out the policy objectives and identified no significant costs to either the public or to the Exchequer.

8.2 The impact on the public sector is minimal as the health services throughout the UK already have well developed emergency planning arrangements in place.

Copies of the Regulatory Impact Assessment in relation to this Order have been placed in the libraries of both Houses of Parliament and copies may be obtained from the Department of Health, Medicines and Healthcare products Regulatory Agency, Information Centre, Room 10-202 Market Towers, 1 Nine Elms Lane, London SW8 5NQ

9. **Contact**

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