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STATUTORY INSTRUMENTS

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**2004 No. 1**

**MEDICINES**

**The Medicines (Pharmacy and General Sale  
—Exemption) Amendment Order 2004**

<i>Made</i>	- - - -	<i>6th January 2004</i>
<i>Laid before Parliament</i>		<i>9th January 2004</i>
<i>Coming into force</i>	- -	<i>31st January 2004</i>

As regards England, Scotland and Wales, the Secretary of State concerned with health in England, and, as regards Northern Ireland, the Department of Health, Social Services and Public Safety, acting jointly, in exercise of the powers conferred upon them by sections 57(1) and (2) and 129(4) of the Medicines Act 1968(1) or, as the case may be, those conferred by the said provisions and now vested in them(2), 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 taking into account the advice of the Committee on Safety of Medicines and of the Medicines Commission pursuant to section 129(7) of that Act, hereby make the following Order:—

**Citation, commencement and interpretation**

1.—(1) This Order may be cited as the Medicines (Pharmacy and General Sale—Exemption) Amendment Order 2004 and shall come into force on 31st January 2004.

(2) In this Order, “the principal Order” means the Medicines (Pharmacy and General Sale—Exemption) Order 1980(3).

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- (1) 1968 c. 67. The expressions “the appropriate Ministers” and “the Health Ministers”, which are relevant to the powers being exercised in the making of this Order, are defined in section 1 of that Act as amended by article 2(2) of, and Schedule 1 to, S.I.1969/388, by article 5 of, and paragraph 1(1) of the Schedule to, S.I. 1999/3142, and by article 5(1) of, and paragraph 15 of Schedule 1 to, S.I. 2002/794.
- (2) In the case of the Secretary of State concerned with health in England, by virtue of article 2(2) of, and Schedule 1 to, S.I. 1969/388, and articles 2(1) and 5 of, and paragraph 1(1) of the Schedule to, S.I. 1999/3142; and in the case of the Department for Health, Social Services and Public Safety, by virtue of the powers vested in the Minister in charge of that Department by virtue of section 95(5) of, and paragraph 10 of Schedule 12 to, the Northern Ireland Act 1998 (c. 47), which may now be exercised by the Department by virtue of section 1(8) of, and paragraph 4(1)(b) of the Schedule to, the Northern Ireland Act 2000 (c. 1); the Department was renamed by virtue of article 3(6) of S.I. 1999/283 (N.I.1).
- (3) 1980/1924; relevant amending instruments are S.I.2000/1919 and 2003/697.

### **Amendment of article 1 of the principal Order**

2. In article 1 of the principal Order (citation, commencement and interpretation), in paragraph (2), in sub-paragraph (a)—

- (a) after the definition of “external use” insert the following definition—  
 ““first level nurse” means a person registered in Parts 1,3,5,8,10,11,12,13,14 or 15 of the professional register;”;
- (b) after the definition of “NHS trust”(4) insert the following definition—  
 ““nurse prescriber” means a person—  
 (a) who is a first level nurse, and  
 (b) against whose name is recorded in the professional register an annotation signifying that he is qualified to order drugs, medicines and appliances;”;
- (c) after the definition of “prison service”(5) insert the following definition—  
 ““professional register” means the register maintained by the Nursing and Midwifery Council pursuant to paragraph 10 of Schedule 2 to the Nursing and Midwifery Order 2001(6);”;
- (d) after the definition of “relevant manager”(7) insert the following definition—  
 ““relevant register” means—  
 (a) in relation to a first level nurse, the professional register, and  
 (b) in relation to a pharmacist, the register maintained in pursuance of section 2(1) of the Pharmacy Act 1954(8) or the register maintained in pursuance of Articles 6 and 9 of the Pharmacy (Northern Ireland) Order 1976(9);”;
- (e) after the definition of “Special Health Authority”(10) insert the following definition—  
 ““supplementary prescriber” means—  
 (a) a first level nurse, or  
 (b) a pharmacist,  
 against whose name is recorded in the relevant register an annotation signifying that he is qualified to order drugs, medicines and appliances as a supplementary prescriber;”.

### **Insertion of article 4AA of the principal Order**

3. After article 4 of the principal Order (exemption for products used by midwives in the course of their professional practice), insert the following article—

#### **“Exemption for sale, offer for sale or supply in hospitals and health centres**

**4AA.** The restrictions imposed by sections 52 and 53 shall not apply to the sale, offer for sale, or supply of a medicinal product, in the course of the business of a hospital or health centre, where the product is sold, offered for sale, or supplied for the purpose of being administered (whether in the hospital or health centre or elsewhere) to a particular person in

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(4) The definition of “NHS Trust” was inserted by S.I. 2000/1919.

(5) The definition of “prison service” was inserted by S.I. 2003/697.

(6) S.I. 2002/253.

(7) The definition of “relevant manager” was inserted by S.I. 2003/697.

(8) 1954 c. 61.

(9) S.I. 1976/1213 (N.I.22).

(10) The definition of “Special Health Authority” was inserted by S.I. 2000/1919.

accordance with the written directions of a supplementary prescriber or a nurse prescriber relating to that person.”.

Signed by authority of the Secretary of State for Health

31st December 2003

*Warner*  
Parliamentary Under Secretary of State,  
Department of Health

Sealed with the Official Seal of the Department of Health, Social Services and Public Safety

6th January 2004

*D.C. Gowdy*  
Permanent Secretary,  
Department of Health, Social Services and  
Public Safety

**Status:** This is the original version (as it was originally made). This item of legislation is currently only available in its original format.

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## EXPLANATORY NOTE

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

This Order amends the Medicines (Pharmacy and General Sale—Exemption) Order 1980 and provides for an exemption to sections 52 and 53 of the Medicines Act 1968 (restrictions on the sale or supply of medicinal products) for the sale, offer for sale or supply of medicines in the course of the business of a hospital or health centre, where such sale or supply is in accordance with the written directions of a supplementary prescriber or an independent nurse prescriber.

A Regulatory Impact Assessment in relation to this Order has 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.