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STATUTORY INSTRUMENTS

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**1991 No. 962**

**MEDICINES**

**The Medicines (Products Other Than Veterinary Drugs) (Prescription Only) Amendment Order 1991**

<i>Made</i>	- - - -	<i>8th April 1991</i>
<i>Laid before Parliament</i>		<i>10th April 1991</i>
<i>Coming into force</i>	- -	<i>1st May 1991</i>

The Secretary of State concerned with health in England, the Secretaries of State respectively concerned with health and with agriculture in Wales and in Scotland, 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 the powers conferred upon them by sections 1(2), 58(1), 129(4) and 132(1) 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 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. This Order, which may be cited as the Medicines (Products Other Than Veterinary Drugs) (Prescription Only) Amendment Order 1991, amends the Medicines (Products Other Than Veterinary Drugs) (Prescription Only) Order 1983(3) (hereinafter referred to as “the principal Order”) and shall come into force on 1st May 1991.

**Amendment of article 3 of the principal Order**

2. In article 3(1)(a) of the principal Order (medicinal products on prescription only), after the words “subject to article 4(1)” the words “and (1A)” are deleted and there are inserted the words “, (1A), (1B), (1C) and (1D),”.

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(1) 1968 c. 67; see the meaning assigned to appropriate Ministers by sections 1(2) and 132(1) and to Ministers by section 1(1).  
(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); 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).  
(3) S.I. 1983/1212, as amended by S.I. 1984/756, 1986/586, 1987/674 and 1250, 1988/2017 and 1989/1852.

### **Amendment of article 4 of the principal Order**

3. In article 4 of the principal Order (medicinal products that are not prescription only), the following paragraph is inserted after paragraph(1C):—

“(1D) Notwithstanding Article 3(1)(a), a medicinal product shall not be a prescription only medicine by reason that it consists of or contains the substance Hyoscine Butylbromide where—

- (a) its route of administration is internal otherwise than by inhaler;
- (b) it is sold or supplied in a container or package containing not more than 240 mg; and
- (c) its container or package is labelled to show a maximum daily dose of 80 mg and a maximum dose of 20 mg.”.

### **Amendment of Part I of Schedule 1 to the principal Order**

4. In Part I of Schedule 1 to the principal Order (which lists substances which render a medicinal product a prescription only medicine except in circumstances also listed)—

- (a) the following substances are inserted at the appropriate points in the alphabetical order of the substances listed in Column 1, and in the case of Vaccines at the appropriate points in the list of vaccines,—

Amlodipine Besylate  
Anistreplase  
Cefuroxime Axetil  
Domperidone Maleate  
Enoxacin  
Flutamide  
Isradipine  
Levobunolol Hydrochloride  
Loxapine Succinate  
Metoprolol Succinate  
Metoprolol Fumarate  
Milrinone Lactate  
Nedocromil Sodium  
Octreotide  
Pamidronate Disodium  
Pentamidine Isethionate  
Perindopril  
Propofol  
Quinapril  
Teicoplanin  
Temocillin Sodium  
Terodiline Hydrochloride  
Tribavirin  
Vaccines – Hepatitis B Vaccine

Meningococcal Polysaccharide Vaccine

Rubella, Mumps, Measles Vaccine

Vigabatrin

Zopiclone

Zuclopenthixol Decanoate;

- (b) the entry“Labetolol Hydrochloride” is substituted by the entry“Labetalol Hydrochloride”; and
- (c) the entry“Hyoscine Butylbromide” is amended by the deletion in Column 3 (Use, pharmaceutical form or route of administration) of the words“(b) otherwise than by inhaler”, and in Column 4 (Maximum dose and maximum daily dose) of the words“(b) 3 mg (MD) 9 mg (MDD) (b)”.

#### **Amendment of Part III of Schedule 1 to the principal Order**

5. In Part III of Schedule 1 to the principal Order (medicinal products, specified by name and product licence number, which are prescription only medicines), the entry

“Nicorette

0458/0020

0458/0021”

“Nicorette Plus

0458/0021”.

#### **Amendment of Table A of Part IV of Schedule 1 to the principal Order**

6. In Table A of Part IV of Schedule 1 to the principal Order (medicinal products specified by name and product licence number which are not prescription only medicines), immediately after the entry“Wasp-Eze Hydrocortisone Cream 0232/0058” the following entry shall be inserted

“Wasp-Eze Hydrocortisone Cream

8452/0012”.

Signed by authority of the Secretary of State for Health.

8th April 1991

*Virginia Bottomley*  
Minister of State,  
Department of Health

5th April 1991

*David Hunt*  
Secretary of State for Wales

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**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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Signed by authority of the Secretary of State for Scotland.

8th April 1991

*Allan Stewart*  
Parliamentary Under-Secretary of State, Scottish  
Office

In Witness whereof the Official Seal of the Minister of Agriculture, Fisheries and Food is hereunto affixed on 8th April 1991.

*Trumpington*  
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 this eighth day of April 1991.

*F. A. Elliott*  
Permanent Secretary

Sealed with the Official Seal of the Department of Agriculture for Northern Ireland this fifth day of April 1991.

*W. J. Hodges*  
Permanent Secretary

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## EXPLANATORY NOTE

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

This Order further amends the Medicines (Products Other Than Veterinary Drugs) (Prescription Only) Order 1983 (the principal Order) which specifies descriptions and classes of prescription only medicines subject to section 58(2) of the Medicines Act 1968, that is to say, 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.

The amendments made by this Order are as follows:—

Article 2 amends article 3 of the principal Order consequentially on the changes made to article 4 of the principal Order.

Article 3 amends article 4 of the principal Order which specifies exemptions from the provisions of section 58(2) so as to exempt certain products containing the substance Hyoscine Butylbromide from being prescription only medicines.

Article 4 amends Part I of Schedule 1 to the principal Order which lists substances which render medicinal products prescription only medicines except in circumstances also listed.

Article 5 amends Part III of Schedule 1 to the principal Order which lists the name and product licence number of medicinal products which are prescription only medicines.

Article 6 adds an entry to Part IV of Schedule 1 to the principal Order which lists the name and product licence number of medicinal products which are not prescription only medicines.