STATUTORY INSTRUMENTS

1994 No. 787

MEDICINES

The Medicines (Control of Substances for Manufacure and Exportation of Specified Products for Human Use) Amendment Order 1994

Made - - - - 16th March 1994
Laid before Parliament 17th March 1994
Coming into force - - 11th April 1994

The Secretaries of State concerned with health in England, in Wales and in Scotland respectively and the Department of Health and Social Services for Northern Ireland, acting jointly in exercise of powers conferred upon them by sections 49 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 those Secretaries of State and that Department together with the Minister of Agriculture, Fisheries and Food, the Secretaries of State concerned with agriculture in Scotland and in Wales respectively and the Department of Agriculture for Northern Ireland, acting jointly in exercise of powers conferred upon them by sections 105(1)(a) and 129(4) of the Medicines Act 1968(3) or, as the case may be, those conferred by the said provisions and now vested in them(4), and in each case in exercise 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(5), hereby make the following Order:

^{(1) 1968} c. 67. The expression "the Health Ministers", used in section 49, is defined in section 1(1)(a) of that Act as amended by Schedule 1 to S.1.1969/388.

⁽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) and in the case of the Department of Health and Social Services for Northern Ireland 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⁾ The expression "the Ministers", used in section 105, is defined in section 1(1) of that Act as amended by S.I.1969/388.

⁽⁴⁾ 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 Department of Agriculture for Northern Ireland 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).

⁽⁵⁾ See section 129(6) of the Medicines Act 1968.

Citation and commencement

1. This Order may be cited as the Medicines (Control of Substances for Manufacture and Exportation of Specified Products for Human Use) Amendment Order 1994 and shall come into force on 11th April 1994.

Amendment of the Medicines (Control of Substances for Manufacture) Order 1971

- **2.**—(1) The Medicines (Control of Substances for Manufacture) Order 1971(6) is amended in accordance with the following paragraphs of this article.
 - (2) Schedule 1 is amended as follows—
 - (a) in the paragraphs in Column 2 corresponding to paragraphs 1 to 19 in Column 1, the words "human beings or" are omitted;
 - (b) in the paragraph in Column 2 corresponding to paragraphs 20 and 21 in Column 1, the words "human beings or" are omitted
 - (c) in the paragraph in Column 2 corresponding to paragraph 22 in Column 1, the words "human or" are omitted
 - (d) in the paragraphs in Column 2 corresponding to paragraphs 23 to 34 in Column 1, the words "human or" are omitted and
 - (e) paragraph 35 in Column 1 and the paragraph in Column 2 corresponding to it are omitted.
 - (3) In Schedule 2, the definition of "Preparations of blood" is omitted.

Amendment of the Medicines (Control of Substances for Manufacture) Order 1985

- **3.** Column 2 of Schedule 1 to the Medicines (Control of Substances for Manufacture) Order 1985(7) is amended as follows—
 - (a) in the paragraphs corresponding to paragraphs 1 and 2 in Column 1, the words "human beings or" are omitted; and
 - (b) in the paragraph corresponding to paragraph 3 in Column 1, the words "human or" are omitted.

Revocation of the Medicines (Exportation of Specified Products for Human Use) Order 1971

4. The Medicines (Exportation of Specified Products for Human Use) Order 1971(8) is revoked.

Signed by authority of the Secretary of State for Health

Tom Sackville
Parliamentary Under Secretary of State
Department of Health

12th March 1994

⁽⁶⁾ S.I.1971/1200.

⁽⁷⁾ S.I. 1985/1403.

⁽⁸⁾ S.I. 1971/1198.

15th day of March 1994.

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

John Redwood 15th March 1994 Secretary of State for Wales Fraser of Carmyllie 15th March 1994 Minister of State The Scottish Office In witness whereof the Official Seal of the Minister of Agriculture, Fisheries and Food is hereunto affixed on L.S. Gillian Shephard 16th March 1994. Minister of Agriculture, Fisheries and Food Sealed with the Official Seal of the Department of Health and Social Services for Northern Ireland this L.S. F. A. Elliott 15th day of March 1994. Permanent Secretary Sealed with the Official Seal of the Department of Agriculture for Northern Ireland this L.S. J. Murray

Permanent Secretary

EXPLANATORY NOTE

(This note is not part of the Order)

This Order amends the Medicines (Control of Substances for Manufacture) Orders 1971 and 1985, limiting the application of those Orders to substances for veterinary use. Those Orders extend the application of specified provisions of the Medicines Act 1968 to certain substances which are not themselves medicinal products but which are used as ingredients in the manufacture of medicinal products.

The Order revokes the Medicines (Exportation of Specified Products for Human Use) Order 1971, which excepted certain classes of medicinal products for human use (antigens, antitoxins, Sera, antisera, toxins and vaccines) from the postponement of the operation of sections 7 to 47 of the Medicines Act 1968. The effect of the revocation is that the operation of the restrictions in relation to the exportation of the medicinal products specified in that order is postponed under section 48 of that Act, and consequently exportation of such products need not be in accordance with a product licence granted under that Act (although for exportation of such products to a member State of the European Community, a wholesale dealer's licence is required by virtue of section 49A of that Act).