SCHEDULE 7

Regulation 11

CONSEQUENTIAL AMENDMENTS TO REGULATIONS

1. In the Medicines (Exemption from Licences) (Wholesale Dealing in Confectionery) Order 1975(**1**) after paragraph (2) of regulation 1 there shall be inserted the following paragraph—

"(2A) In this Order a reference to a medicinal product includes a reference to a relevant medicinal product within the meaning of the Medicines for Human Use (Marketing Authorizations Etc.) Regulations 1994, and a reference to a product licence includes a reference to a marketing authorization within the meaning of those Regulations.".

2. In the Medicines (Child Safety) Regulations 1975(**2**) in sub-paragraph (d) of paragraph (3) of regulation 2, after the words "by virtue of the relevant product licence" there shall be inserted the words "or marketing authorization (within the meaning of the Medicines for Human Use (Marketing Authorizations Etc.) Regulations 1994)".

3. In the Medicines (Labelling) Regulations 1976(**3**)—

(a) for the heading to regulation 1 there shall be substituted the heading "Citation and scope";

(b) regulation 1 shall be re-numbered paragraph (1) of regulation 1; and

(c) after that paragraph there shall be inserted the following paragraph—

"(2) Nothing in these Regulations applies to a medicinal product for human use to which the Medicines for Human Use (Marketing Authorizations Etc.) Regulations 1994 apply.".

4. In the Medicines (Manufacturer's Undertakings for Imported Products) Regulations 1977(**4**) for paragraph (1) of regulation 2 there shall be substituted the following paragraph—

"(1) In these Regulations, unless the context otherwise requires—

(a) "medicinal product" includes a relevant medicinal product within the meaning of the Medicines for Human Use (Marketing Authorizations Etc.) Regulations 1994 and, where a product licence relates to any substance or article which is not a medicinal product, the substance or article to which the licence relates or is intended to relate;

(b) "product licence" includes a marketing authorization within the meaning of the Medicines for Human Use (Marketing Authorizations Etc.) Regulations 1994; and

(c) other expressions have the same meanings as in the Medicines Act 1968.".

5. In the Medicines (Leaflets) Regulations 1977(**5**)

(a) for the heading to regulation 1 there shall be substituted the heading "Citation, commencement and scope";

(b) regulation 1 shall be re-numbered paragraph (1) of regulation 1; and

(c) after that paragraph there shall be inserted the following paragraph—

"(2) Nothing in these Regulations applies to a medicinal product for human use to which the Medicines for Human Use (Marketing Authorizations Etc.) Regulations 1994 apply.".

(**1**) S.I. 1975/762.
(**2**) S.I. 1975/2000. The relevant amending instruments are S.I. 1976/1643, 1987/877, and 1994/1402.
(**3**) S.I. 1976/1726. The relevant amending instruments are S.I. 1977/996, 1983/1729, 1988/1009 and 1992/3273.
(**4**) S.I. 1977/1038. The relevant amending instrument is S.I. 1992/2845.
(**5**) S.I. 1977/655.

6. In the medicines (Fluted Bottles) Regulations 1978(**6**), in paragraph (g) of regulation 3, after the words "product licence," there shall be inserted the words "a marketing authorization within the meaning of the Medicines for Human Use (Marketing Authorizations Etc.) Regulations 1994,".

7. In the Importation of Animal Products and Poultry Products Order 1980(**7**), after the words "or the Marketing Authorisations for Veterinary Medicinal Products Regulations 1994" there shall be inserted the words "or the Medicines for Human Use (Marketing Authorizations Etc.) Regulations 1994".

8. In the Medicines (Sale or Supply) (Miscellaneous Provisions) Regulations 1980(**8**), in sub-paragraph (a) of paragraph (1) of regulation 5, after the words "product licence" there shall be inserted the words "or the holder of a marketing authorization within the meaning of the Medicines for Human Use (Marketing Authorizations Etc.) Regulations 1994".

9. In the Medicines (Pharmacy and General Sale) Exemption Order 1980(**9**)—

(a) in paragraph 11 of Column 1 of Schedule 1, after the words "Holders of product licences" there shall be inserted the words, "holders of marketing authorizations within the meaning of the Medicines for Human Use (Marketing Authorizations Etc.) Regulations 1994"; and

(b) in paragraph 11 of Column 2 of that Schedule, at the end there shall be added the words "or marketing authorizations".

10. In the Health and Safety (Dangerous Pathogens) Regulations 1981(**10**), in regulation 2(1) in the definition of "listed pathogen", after the words "marketing authorisation to which the Marketing Authorisations for Veterinary Medicinal Products Regulations 1984" there shall be inserted the words "or the Medicines for Human Use (Marketing Authorizations Etc.) Regulations 1994".

11. In the Food Labelling Regulations 1984(**11**), in Column 2 of paragraph 7, at the end there shall be added the words "or a marketing authorization within the meaning of the Medicines for Human Use (Marketing Authorizations Etc.) Regulations 1994".

12. In the Natural Mineral Waters Regulations 1985(**12**), in sub-paragraph (c) of paragraph (1) of regulation 3, at the end there shall be added the words "or a marketing authorization within the meaning of the Medicines for Human Use (Marketing Authorizations Etc.) Regulations 1994".

13. In the Merchant Shipping (Medical Stores) Regulations 1986(**13**), in sub-paragraph (d) of paragraph (3) of regulation 6, after the words "product licence" there shall be inserted the words "or marketing authorization".

14. In the Trade Descriptions (Places of Production) (Marking) Order 1988(**14**), in article 1(2)(d) after the words "Marketing Authorisations for Veterinary Medicinal Products Regulations 1994" there shall be inserted the words "or the Medicines for Human Use (Marketing Authorizations Etc.) Regulations 1994".

15. In the Medicines (Exemption from Licences) (Wholesale Dealing) Order 1990(**15**)—

(a) in paragraph (2) of regulation 1, after the definition of "intermediate feed" there shall be inserted the following definition—

(**6**) S.I. 1978/40.
(**7**) S.I. 1980/14. The relevant amending instrument is S.I. 1994/
(**8**) S.I. 1980/1923. The relevant amending instruments are S.I. 1982/28, 1990/1124 and 1992/2938.
(**9**) S.I. 1980/1924. The relevant amending instruments are S.I. 1982/27, 1989/1852 and 1994/2409.
(**10**) S.I. 1981/1011.
(**11**) S.I. 1984/1305, to which there are amendments not relevant to these Regulations.
(**12**) S.I. 1985/71. The relevant amending instruments are S.I. 1991/1476 and 1992/2596.
(**13**) S.I. 1986/144.
(**14**) S.I. 1988/1771.
(**15**) S.I. 1990/566.

""marketing authorization" has the same meaning as in the Medicines for Human Use (Marketing Authorizations Etc.) Regulations 1994;";

(b) in the definition of "medicinal product" in that paragraph, after head (c) there shall be inserted—

"(d) relevant medicinal products within the meaning of the Medicines for Human Use (Marketing Authorizations Etc.) Regulations 1994;";

(c) in paragraph (1) of regulation 2—

(i) in sub-paragraph (a), after the words "product licence" (in both places where they occur) there shall be inserted the words "or marketing authorization"; and

(ii) in sub-paragraph (b), after the words "product licence" (in both places where they occur) there shall be inserted the words "or marketing authorization".

16. In the Children's Homes Regulations 1991(**16**), in paragraph (1) of regulation 2, in the definition of "medicinal product", after the words "Medicines Act 1968" there shall be inserted the words "or a marketing authorization under Council Regulation (EEC) No. 2309/93 or the Medicines for Human Use (Marketing Authorizations Etc.) Regulations 1994".

17. In the Medicines (Applications for Grant of Product Licences-Products for Human Use) Regulations 1993(**17**), after paragraph (1) of regulation 1 there shall be inserted the following paragraph—

"(1A) Nothing in these Regulations applies to a medicinal product for human use to which the Medicines for Human Use (Marketing Authorizations Etc.) Regulations 1994 apply.".

18. In the Specified Animal Pathogens Order 1993(**18**), in sub-paragraph (a) of paragraph (2) of regulation 5, after the words "the Medicines Act 1968" there shall be inserted the words "or a marketing authorization has been granted under Council Regulation (EEC) No. 2309/93 or the Medicines for Human Use (Marketing Authorizations Etc.) Regulations 1994".

19. In the Drinking Water in Containers Regulations 1994(**19**), in paragraph (b) of regulation 3, after the words "product licence within the meaning of that Act" there shall be inserted the words "or a marketing authorization within the meaning of the Medicines for Human Use (Marketing Authorizations Etc.) Regulations 1994".

20. In the Medicines (Advertising) Regulations 1994(**20**)—

(a) in paragraph (1) of regulation 2, after the definition of "essential information" there shall be inserted the following definition—

""marketing authorization" means a marketing authorization granted by the European Commission under Council Regulation (EEC) No. 2309/93 or by the licensing authority under the Medicines for Human Use (Marketing Authorizations Etc.) Regulations 1994 and includes a product licence granted by the licensing authority under Part II of the Act;";

(b) in paragraph (1) of regulation 3, for the words "product licence" there shall be substituted the words "marketing authorization"; and

(c) in regulation 4 for the words "product licence" there shall be substituted the words "marketing authorization";

(**16**) S.I. 1991/1506.
(**17**) S.I. 1993/2538.
(**18**) S.I. 1993/3250.
(**19**) S.I. 1994/743.
(**20**) S.I. 1994/1932.

(d) in sub-paragraph (l) of paragraph (1) of regulation 9, for the words "product licence" there shall be substituted the words "marketing authorization";

(e) in regulation 12, for the words "product licence" there shall be substituted the words "marketing authorization"; and

(f) in Schedule 2—

(i) in paragraph 1, for the word "licence" there shall be substituted the word "authorization";

(ii) in paragraph 2, for the words "product licence" there shall be substituted the words "marketing authorization"; and

(iii) in paragraph 5, for the word "licence" there shall be substituted the word "authorization"; and

21. In the General Product Safety Regulations 1994(**21**), in regulation 11(c)(ii)(aa), after the words "the provisions of the 1968 Act" there shall be inserted the words "or which are the subject of a marketing authorization within the meaning of the Medicines for Human Use (Marketing Authorizations Etc.) Regulations 1994".

(b) regulation 1 shall be re-numbered paragraph (1) of regulation 1; and

(c) after that paragraph there shall be inserted the following paragraph—

"(2) Nothing in these Regulations applies to a medicinal product for human use to which the Medicines for Human Use (Marketing Authorizations Etc.) Regulations 1994 apply.".

22. In the Medicines (Restrictions on the Administration of Veterinary Medicinal Products) Regulations 1994(b), in regulation 3(1)(b), after the words "a medicinal product licensed" there shall be inserted the words "or authorized in accordance with the Medicines for Human Use (Marketing Authorizations Etc.) Regulations 1994".

(**21**) S.I. 1994/2328.