SCHEDULE 7

Regulation 12

CONSEQUENTIAL AMENDMENTS TO ORDERS AND REGULATIONS

1. In the Medicines (Retail Sale or Supply of Herbal Remedies) Order 1977(**1**), after article 1 insert the following article—

"**Application**

1A. Nothing in this Order applies to a medicinal product for human use to which the Medicines (Traditional Herbal Medicinal Products for Human Use) Regulations 2005 apply.".

2. In the Medicines (Sale or Supply) (Miscellaneous Provisions) Regulations 1980(**2**), in regulation 5 (restrictions on persons to be supplied with certain medicinal products), in paragraph (1)(a), after "Marketing Authorizations Etc.) Regulations 1994" insert "or the holder of a traditional herbal registration within the meaning of the Medicines (Traditional Herbal Medicinal Products for Human Use) Regulations 2005".

3.—(1) The Medicines (Pharmacy and General Sale-Exemption) Order 1980(**3**) is amended as follows.

(2) In article 1 (citation, commencement and interpretation), in paragraph (2), after the definition of "supply" insert the following definition—

""traditional herbal registration" means a registration granted by the licensing authority under The Medicines (Traditional Herbal Medicinal Products for Human Use) Regulations 2005;".

(3) In article 4A (exemption for the supply of medicinal products by national health service bodies)(**4**), in paragraph (2)(e), after "marketing authorization" insert ", a traditional herbal registration".

(4) In article 4B (exemption for health professionals who supply medicinal products under a Patient Group Direction in order to assist doctors or dentists in providing national health services)(**5**), in paragraph (2)(f), after "marketing authorization" insert ", a traditional herbal registration".

(5) In article 4C (exemption for the supply of medicinal products by independent hospitals, clinics and agencies)(**6**), in paragraph (2)(e), after "marketing authorization" insert ", a traditional herbal registration".

(6) In article 4D (exemption for health professionals who supply medicinal products under a Patient Group Direction in order to assist the provision of health care by or on behalf of the police, the prison services or the armed forces)(**7**), in paragraph (2)(f), after "marketing authorization" insert ", a traditional herbal registration".

4.—(1) The Medicines (Products Other Than Veterinary Drugs) (General Sale List) Order 1984(**8**) is amended as follows.

(2) In article 1 (citation, commencement and interpretation), in paragraph (2)(a)—

(**1**) S.I.1977/2130.
(**2**) S.I. 1980/1923, paragraph (1) of regulation 5 was amended by S.I. 1994/3142 and 3144.
(**3**) S.I. 1980/1924; relevant amending instruments are S.I. 2000/1919 and 2003/697.
(**4**) Article 4A was inserted by article 2(c) of S.I. 2000/1919.
(**5**) Article 4B was inserted by article 2(c) of S.I. 2000/1919.
(**6**) Article 4C was inserted by article 3 of S.I. 2003/697.
(**7**) Article 4D was inserted by article 3 of S.I. 2003/697.
(**8**) S.I. 1984/769; relevant amending instrument is S.I. 2002/933.

(a) in the definition of "marketing authorization"(**9**), after "Evaluation of Medicinal Products" insert "or by the European Medicines Agency under Regulation (EC) No. 726/2004 of the European Parliament and of the Council laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency(**10**)"; and

(b) after the definition of "product licence of right" insert the following definition—

""traditional herbal registration" means a registration granted by the licensing authority under the Medicines (Traditional Herbal Medicinal Products for Human Use) Regulations 2005; and".

(3) In article 2 (general sale list)—

(a) after paragraph (a) insert the following paragraph—

"(aa) medicinal products in respect of which a traditional herbal registration has been granted, which in the traditional herbal registration are classified as being general sale list medicines;"; and

(b) in paragraph (b) after "marketing authorization" insert "or traditional herbal registration".

5. In the Dangerous Substances and Preparations (Safety) (Consolidation) Regulations 1994(**11**), in regulation 1 (citation, commencement and interpretation), in paragraph (2), in the definition of "medicinal product", in paragraph (a), after sub-paragraph (i) insert the following sub-paragraph—

"(ia) in respect of which there is for the time being a traditional herbal registration granted under regulation 6 of the Medicines (Traditional Herbal Medicinal Products for Human Use) Regulations 2005, or".

6. In the Medicines (Aristolochia and Mu Tong etc.) (Prohibition) Order 2001(**12**), in article 4 (Exceptions to the prohibitions imposed by articles 2 and 3), in paragraph (4), after "(Marketing Authorisations Etc.) Regulations 1994" insert ", a traditional herbal registration within the meaning of regulation 2(1) of the Medicines (Traditional Herbal Medicinal Products for Human Use) Regulations 2005".

7. In the Medicines for Human Use (Kava-Kava) (Prohibition) Order 2002(**13**), in article 3 (Exceptions to the prohibition imposed by article 2), in paragraph (d)—

(a) at the end of sub-paragraph (iii) insert ", or"; and

(b) after sub-paragraph (iii) insert the following sub-paragraph—

"(iv) a traditional herbal registration within the meaning given in regulation 2(1) of the Medicines (Traditional Herbal Medicinal Products for Human Use) Regulations 2005.".

8. In the Unlicensed Medicinal Products for Human Use (Transmissible Spongiform Encephalopathies) (Safety) Regulations 2003(**14**), in regulation 1 (citation, commencement and interpretation), in paragraph (2)—

(a) in the definition of "unlicensed product"—

(i) in sub-paragraph (a)(ii) after "Medicinal Products" insert "or under Regulation (EC) No. 726/2004 of the European Parliament and of the Council laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency",

(**9**) The definition of "marketing authorization" was inserted by article 2(a) of S.I. 2002/933.
(**10**) OJ No. L136, 30.4.2004, p.1.
(**11**) S.I. 1994/2844, regulation 1(2) was amended by S.I. 1996/2635 and 2004/1031.
(**12**) S.I. 2001/1841.
(**13**) S.I. 2002/3170.
(**14**) S.I. 2003/1680, regulation 1(2) was amended by S.I. 2004/3224.

(ii) at the end of sub-paragraph (b) insert "or", and

(iii) after sub-paragraph (b) insert the following sub-paragraph—

"(c) no traditional herbal registration has been granted by the licensing authority under the Medicines (Traditional Herbal Medicinal Products for Human Use) Regulations 2005;"; and

(b) in the definition of "the TSE Guideline" after "for human use" insert "as substituted by Commission Directive 2003/63/EC amending Directive 2001/83/EC on the Community code relating to medicinal products for human use".