STATUTORY INSTRUMENTS

2002 No. 236

MEDICINES

The Medicines (Codification Amendments Etc.) Regulations 2002

Made - - - -	*7th February 2002*
Laid before Parliament	*7th February 2002*
Coming into force - -	*28th February 2002*

The Secretary of State, in exercise of the powers conferred by section 2(2) of the European Communities Act 1972(**1**), being designated for the purposes of that section in relation to medicinal products(**2**), hereby makes the following Regulations—

Citation, commencement and interpretation

1.—(1) These Regulations may be cited as the Medicines (Codification Amendments Etc.) Regulations 2002 and shall come into force on 28th February 2002.

(2) In these Regulations "the 2001 Directive" means Directive 2001/83/EC of the European Parliament and of the Council on the Community code relating to medicinal products for human use(**3**).

Amendment of the Medicines Act 1968

2. The Medicines Act 1968(**4**) is amended as follows—

(a) in the following sections for "Chapters II to V of the 1965 Directive apply", in each place where those words occur, there is substituted "the 2001 Directive applies"—

(i) section 8(3A) and (3C) (manufacture and wholesale dealing),

(ii) section 14(2) (exports to a Member State),

(iii) section 28(3)(j) and (3A) (general power to suspend, revoke or vary licences),

(iv) section 49A(a) (exporting certain products to Member States),

(v) section 58A(1)(b) (specification of prescription-only products), and

(**1**) 1972 c. 68.
(**2**) *See* the European Communities (Designation) Order 1972 (S.I.1972/1811).
(**3**) OJ No. L311, 28.11.2001, p. 67.
(**4**) 1968 c. 67.

(vi) section 86(4) (leaflets);

(b) in section 18(3) (application for licence) for "Article 9 of the Second Council Directive 75/319/EEC of 20 May 1975" there is substituted "Article 28 of the 2001 Directive";

(c) in section 24 (duration and renewal of licence)—

(i) in subsection (1A) for "the 1992 Directive" there is substituted "Title V of the 2001 Directive",

(ii) in subsection (3)(C) for "the 1965 Directive or the 1992 Directive" there is substituted "the 2001 Directive other than Titles VI, VII and VIII of that Directive", and

(iii) subsection (7) is deleted;

(d) in section 132 (general interpretation provisions)—

(i) the definition of "the 1965 Directive" is deleted, and

(ii) after the definition of "the 1981 Directive" there is inserted the following definition—

""the 2001 Directive" means Directive 2001/83/EC of the European Parliament and of the Council on the Community code relating to medicinal products for human use".

Amendment of the Standard Provisions Regulations 1971

3. The Medicines (Standard Provisions for Licences and Certificates) Regulations 1971(**5**) are amended as follows—

(a) in regulation 2(1) (interpretation)—

(i) after the definition of ""clinical trial certificate of right" and "animal test certificate of right"" there is inserted the following definition—

""the 2001 Directive" means Directive 2001/83/EC of the European Parliament and of the Council on the Community code relating to medicines for human use;",

(ii) in the definition of "exempt imported products" for "article 1(2) of Council Directive 65/65/EEC" there is substituted "Article 1.2 of the 2001 Directive",

(iii) for the definition of "product to which Chapters II to V of the 1965 Directive apply" there is substituted the following definition—

""product to which the provisions of the 2001 Directive apply" means a medicinal product to which, in accordance with Article 2 of the 2001 Directive, the provisions of that Directive apply and accordingly does not include the products mentioned in Article 3 of that Directive;", and

(iv) the definition of "Second Council Directive" is omitted;

(b) in Schedule 1 (standard provisions for product licences), in paragraph 16 for "Part 4G of the Annex to Council Directive 75/318/EEC" there is substituted "Part 4G of Annex I to the 2001 Directive";

(c) in Schedule 2 (standard provisions for manufacturer's licences), in paragraph 16(1) and (4) for "Articles 23 and 24 of the Second Council Directive", in each place where those words occur, there is substituted "Articles 49 and 50 of the 2001 Directive";

(d) in Schedule 3 (standard provisions for wholesale dealer's licences)—

(**5**) S.I.1971/972; relevant amendments were made by S.I. 1977/1053, 1993/833, 1994/103 and 1992/3272.

(i) in paragraphs 4A, 4B(1), 7A(1), 7B and 7C(1) for "Chapters II to V of the 1965 Directive", in each place where those words occur, there is substituted "the provisions of the 2001 Directive",

(ii) in paragraphs 7(3)(a), 8(1) and (6) for "Articles 23 and 24 of the Second Council Directive", in each place where those words occur, there is substituted "Articles 49 and 50 of the 2001 Directive", and

(iii) in paragraph 8(1) for "Article 24" there is substituted "Article 50"; and

(e) in Schedule 5, Part I (standard provisions for product licences for medicinal products to which regulation 5 of the Standard Provisions Regulations applies), in paragraph 3A for "Council Directive 65/65/EEC as amended" there is substituted "the 2001 Directive".

Amendment of the Manufacturer's and Wholesaler Dealer's Regulations 1971

4. The Medicines (Applications for Manufacturer's and Wholesale Dealer's Licences) Regulations 1971(**6**) are amended as follows—

(a) in regulation 2(1) (interpretation)—

(i) after the definition of "application" there is inserted the following definition—

""the 2001 Directive" means Directive 2001/83/EC of the European Parliament and of the Council on the Community code relating to medicinal products for human use;", and

(ii) for the definition of "product to which Chapters II to V of the 1965 Directive apply" there is substituted the following definition—

""product to which the provisions of the 2001 Directive apply" means a medicinal product to which, in accordance with Article 2 of the 2001 Directive, the provisions of that Directive apply and accordingly does not include the products mentioned in Article 3 of that Directive;"; and

(b) in Schedule 2 (particulars required on a wholesale dealer's licence application), in paragraphs 8A, 8B and 8C for "Chapters II to V of the 1965 Directive apply", in each place where those words occur, there is substituted "the 2001 Directive applies".

Amendment of the Labelling Regulations 1976

5. The Medicines (Labelling) Regulations 1976(**7**) are amended as follows—

(a) in regulation 3(1) (interpretation)—

(i) after the definition of "data sheet" there is inserted the following definition—

""the 2001 Directive" means Directive 2001/83/EC of the European Parliament and of the Council on the Community code relating to medicinal products for human use;",

(ii) for the definition of "homoeopathic product to which Council Directive 92/73/EEC applies" there is substituted—

""homoeopathic product to which the 2001 Directive applies" means a medicinal product for human use (which may contain a number of principles) prepared from products, substances or compositions called homoeopathic stocks in accordance with a homoeopathic manufacturing procedure described

(**6**) S.I. 1971/974; a relevant amendment was made by S.I. 1993/832.
(**7**) S.I. 1976/1726; relevant amendments were made by S.I. 1992/3273, 1994/104 and 3144 and 1996/2194.

by the European Pharmacopoeia or, in the absence thereof, by any pharmacopoeia used officially in a member State, other than one—

(i) prepared in accordance with a magistral or officinal formula as described in Article 3(1) and (2) of the 2001 Directive, or

(ii) which satisfies the criteria laid down in Article 5 of the 2001 Directive;",

(iii) the definition of "product to which Chapters II to V of the 1965 Directive applies" is deleted, and

(iv) in the definition of "relevant medicinal product" for "Chapters II to V of the 1965 Directive" there is substituted "the 2001 Directive";

(b) in regulation 4A (standard labelling requirement), in paragraph (5)—

(i) for the words from "Article 4a of Directive 65/65/EEC" to "Directive 89/341/EEC" inclusive there is substituted "Article 11.1 to 11.7 of the 2001 Directive", and

(ii) in sub-paragraph (b), for "Article 4a of Directive 65/65/EEC" there is substituted "Article 11.1 to 11.7 of the 2001 Directive";

(c) in regulation 4B (standard labelling requirements for radiopharmaceuticals) for "Chapters II to V of the 1965 Directive" there is substituted "the 2001 Directive"; and

(d) in regulation 4F (standard labelling requirements for certain homoeopathic products), in paragraph (1) for "Council Directive 92/73/EEC" there is substituted "the 2001 Directive".

Amendment of the Active Implantable Medical Devices Regulations 1992

6. Paragraph 10 of Schedule 2 to the Active Implantable Medical Devices Regulations 1992(**8**) (essential requirements for active implantable medical devices), is amended as follows—

(a) for "Article 1 of Directive 65/65/EEC" there is substituted "Article 1 of Directive 2001/83/EC on the European Parliament and of the Council on the Community code relating to medicinal products for human use"; and

(b) for the words "Directive 75/318/EEC, as last amended by Directive 91/507/EEC" there is substituted "that Directive".

Amendment of the Product Licences Regulations 1993

7. The Medicines (Applications for Grant of Product Licences—Products for Human Use) Regulations 1993(**9**) are amended as follows—

(a) in regulation 1(2) (interpretation)—

(i) after the definition of "application" there is inserted the following definition—

""the 2001 Directive" means Directive 2001/83/EC of the European Parliament and of the Council on the Community code relating to medicinal products for human use;", and

(ii) in the definition of "the Directives" after "89/381/EEC" there is inserted "notwithstanding their repeal by the 2001 Directive";

(b) in regulation 4(1) and (2) (material in application)—

(i) for "Chapters II to V of the 1965 Directive apply", in each place where those words occur, there is substituted "the 2001 Directive applies",

(**8**) S.I. 1992/3146, to which there are amendments not relevant to these Regulations.
(**9**) S.I. 1993/2538; a relevant amendment was made by S.I. 1997/654.

(ii) for "the Directives", in each place where those words occur, there is substituted "that Directive", and

(iii) in regulation 4(2) for "those Chapters applied" there is substituted "that Directive applies";

(c) regulation 4(7) (requirements for applications before 1st January 1995) is deleted;

(d) in Schedule 1 (information and documents etc. required for applications)—

(i) in paragraph 9(d)(v) for "Directive 89/342/EEC applies" there is substituted "the 2001 Directive applies",

(ii) in paragraph 9(g) for "Directive 89/343/EEC" there is substituted "the 2001 Directive",

(iii) in paragraph 10 for "Article 16 of Directive 75/319/EEC" there is substituted "Article 40 of the 2001 Directive",

(iv) in paragraph 11 for "Article 4a of the 1965 Directive" there is substituted "Article 11 of the 2001 Directive",

(v) in paragraphs 17 and 18 for "Annex to Directive 75/318/EEC", in each place where those words occur, there is substituted "Annex I to the 2001 Directive",

(vi) in paragraph 21 for "Article 3 of Directive 89/343/EEC" there is substituted "Article 9 of the 2001 Directive", and

(vii) in paragraph 22(b) for "Directive 89/343/EEC" there is substituted "the 2001 Directive"; and

(e) in Schedule 2 (exceptions to the requirement to provide particulars of certain tests' and trials' results), in paragraph 1(b) for "the second paragraph of Article 1 of Directive 75/318/EEC" there is substituted "Article 10.2 of the 2001 Directive".

Amendment of the Marketing Authorisations Regulations 1994

8. The Medicines for Human Use (Marketing Authorisations Etc.) Regulations 1994(**10**) are amended as follows—

(a) in regulation 1(2) (interpretation)—

(i) after the definition of "Community marketing authorization" there is inserted the following definition—

> ""the 2001 Directive" means Directive 2001/83/EC of the European Parliament and of the Council on the Community code relating to medicinal products for human use(**11**)

(ii) for the definition of "the relevant Community provisions" there is substituted—

> ""the relevant Community provisions" means the provisions of—
>
> the 2001 Directive;
>
> Regulation (EEC) No. 2309/93(**12**);
>
> Regulation (EC) No. 540/95(**13**);
>
> Regulation (EC) No. 541/95(**14**), as amended(**15**);

(**10**) S.I. 1994/3144; relevant amendments were made by S.I. 1998/3105, 2000/292, and 2001/795.
(**11**) OJ No. L311, 28.11.01, p. 67.
(**12**) OJ No. L214, 24.8.93, p. 1.
(**13**) OJ No. L55, 11.3.95, p. 5.
(**14**) OJ No. L55, 11.3.95, p. 7.
(**15**) *See* Regulation (EC) No. 1146/98 (OJ No. L159, 3.6.98, p. 31).

Regulation (EC) No. 542/95(**16**), as amended(**17**);

Regulation (EC) No. 141/2000(**18**); and

Regulation (EC) No. 847/2000(**19**)

(iii) for the definition of "relevant medicinal product" there is substituted—

""relevant medicinal product" means a medicinal product for human use to which the provisions of the 2001 Directive apply(**20**)

(b) in regulation 4(6) (applications for the grant, renewal or variation of a United Kingdom marketing authorization), for "point 8(a)(iii) of the second paragraph of Article 4 of the 1965 Directive" there is substituted "point (iii) of sub-paragraph (a) of Article 10.1 of the 2001 Directive";

(c) in regulation 4(7) (applications for the grant etc. of a United Kingdom marketing authorization), for "point 8(a) of the second paragraph of Article 4 of the 1965 Directive" there is substituted "sub-paragraph (a) of Article 10.1 of the 2001 Directive";

(d) in regulation 5(4) (consideration, and grant or refusal etc. of an application for a United Kingdom marketing authorization), for "Article 10 of the 1965 Directive" there is substituted "Article 24 of the 2001 Directive";

(e) in regulation 8(2) (control of retail sale or supply of relevant medicinal products) for "Article 3.4 of Council Directive 92/26/EEC" there is substituted "Article 71.4 of the 2001 Directive";

(f) in Schedule 1 (exemptions and exceptions from the provisions of regulation 3), in paragraph 2(e) for "Article 16 of Council Directive 75/319/EEC" there is substituted "Article 40 of the 2001 Directive";

(g) in Schedule 2 (procedural provisions relating to United Kingdom marketing authorizations)—

(i) in paragraph 3 for "Article 13 of Council Directive 75/319/EEC" there is substituted "Article 32 of the 2001 Directive",

(ii) in paragraph 4(a) for "Article 7.2 of the 1965 Directive" there is substituted "Article 17.2 of the 2001 Directive", and

(iii) in paragraph 4(b) for "the provisions of Chapter III of Council Directive 75/319/EEC" there is substituted "the provisions of Title III, Chapter 4 of the 2001 Directive";

(h) in Schedule 3 (offences, penalties etc.)—

(i) in paragraph 6(a) for "Article 4 of the 1965 Directive" there is substituted "Article 8.3 of the 2001 Directive",

(ii) in paragraph 6(b) and (e) for "Article 9a of the 1965 Directive" there is substituted "Article 23 of the 2001 Directive",

(iii) in paragraph 6(c) for "paragraph C.a of Part 2 of the Annex to Council Directive 75/318/EEC" there is substituted "paragraph D of Part 2 of Annex I to the 2001 Directive",

(**16**) OJ No. L55, 11.3.95, p. 15.
(**17**) *See* Regulation (EC) No. 1069/98 (OJ No. L153, 27.5.98, p. 11).
(**18**) OJ No. L103, 28.4.00, p. 1.
(**19**) OJ No. L18, 22.1.00, p. 5.
(**20**) See Articles 2 and 3 of the Directive.

(iv) in each of paragraphs 7, 8, 9 and 10 for "Chapter Va of Council Directive 75/319/EEC" there is substituted "Title IX of the 2001 Directive", and in paragraph 10 for the words "such Chapter," there is substituted "such Chapter or Title,",

(v) in paragraph 10, in sub-paragraph (c) for the words "and promptly," there is substituted "and promptly; or

(d) provide to the licensing authority any other information relevant to the evaluation of the benefits and risks afforded by a medicinal product, including appropriate information on post authorization safety studies,", and

(vi) in paragraphs 11 and 12 for "Council Directive 92/27/EEC" there is substituted "Title V of the 2001 Directive", and

(i) in Schedule 5 (labels), in paragraph 2—

(i) for "Council Directive 92/27/EEC" there is substituted "Title V of the 2001 Directive", and

(ii) for "Council Directive 92/26/EEC" there is substituted "Title VI of the 2001 Directive".

Amendment of the Homoeopathic Medicinal Products for Human Use Regulations 1994

9. The Medicines (Homoeopathic Medicinal Products for Human Use) Regulations 1994(**21**) are amended as follows—

(a) in regulation 1(2) (interpretation) after the definition of "certificate of registration" there is inserted the following definition—

""the 2001 Directive" means Directive 2001/83/EC of the European Parliament and of the Council on the Community code relating to medicinal products for human use;";

(b) in regulation 1(3) (interpretation) for "Council Directive 92/73/EEC" there is substituted "the 2001 Directive";

(c) in regulation 2 (application)—

(i) for "Article 1(4) and (5) of the 1965 Directive" there is substituted "Article 3 of the 2001 Directive", and

(ii) for "Article 2(4)" there is substituted "Article 5"; and

(d) in regulation 5(1)—

(i) for "Article 7 of Council Directive 92/73/EEC" there is substituted "Article 14 of the 2001 Directive", and

(ii) for "Article 9" there is substituted "Article 16".

Amendment of the Advertising Regulations 1994

10. In the Medicines (Advertising) Regulations 1994(**22**), regulation 2(1) (interpretation) is amended as follows—

(a) after the definition of "common name" there is inserted the following definition—

(**21**) S.I. 1994/105; a relevant amendment was made by S.I. 1998/574.
(**22**) S.I. 1994/1932; relevant amendments were made by S.I. 1994/276 and 3144, and 1999/267.

""the 2001 Directive" means Directive 2001/83/EC of the European Parliament and of the Council on the Community code relating to medicinal products for human use;";

(b) in the definition of "essential information compatible with the summary of product characteristics" for "Council Directive 92/28/EEC" there is substituted "Title VIII of the 2001 Directive";

(c) in the definition of "registered homoeopathic medicinal product" for "Council Directive 92/73/EEC" there is substituted "the 2001 Directive";

(d) in the definition of "relevant medicinal product", in both paragraphs (a) and (b)(i) for "Chapters II to V of the 1965 Directive apply", in each place where those words occur, there is substituted "the 2001 Directive applies"; and

(e) in the definition of "summary of product characteristics" for the words from "article 4a of the 1965 Directive" to "Council Directive 89/341/EEC" inclusive there is substituted "Article 11 of the 2001 Directive".

Amendment of the Monitoring of Advertising Regulations 1994

11. In the Medicines (Monitoring of Advertising Regulations) 1994(**23**), regulation 2(6) (application) is amended as follows—

(a) in both sub-paragraphs (a) and (b)(i) for "Chapters II to V of the 1965 Directive apply", in each place where those words occur, there is substituted "Directive 2001/83/EC of the European Parliament and of the Council on the Community code relating to medicinal products for human use applies"; and

(b) in sub-paragraph (c) for "Council Directive 92/73/EEC" there is substituted "Directive 2001/83/EC of the European Parliament and of the Council on the Community code relating to medicinal products for human use".

Amendment of the Restrictions on the Administration of Veterinary Medicinal Products Regulations 1994

12. In the Medicines (Restrictions on the Administration of Veterinary Medicinal Products) Regulations 1994(**24**), regulation 2(1) (interpretation), in the definition of "homoeopathic medicinal product" for "Article 1.1 of Council Directive 92/73/EEC" there is substituted "Article 1.5 of Directive 2001/83/EC of the European Parliament and of the Council on the Community code relating to medicinal products for human use".

Amendment of the Medical Devices Regulations 1994

13. The Medical Devices Regulations 1994(**25**) are amended as follows—

(a) in regulation 2(1) (interpretation), in the definition of "device" for "Council Directive 65/65/EEC" there is substituted "Directive 2001/83/EC of the European Parliament and of the Council on the Community code relating to medicinal products for human use"; and

(b) in regulation 3 (application of the Regulations)—

(i) in paragraph 2(c) for "Council Directive 65/65/EEC as last amended by Council Directive 93/39/EEC" there is substituted "Directive 2001/83/EC of the European Parliament and of the Council on the Community code relating to medicinal products for human use"; and

(**23**) S.I. 1994/1933.
(**24**) S.I. 1994/2987.
(**25**) S.I. 1994/3107, amended by S.I. 2000/1315.

(ii) in paragraph (3) for "Council Directive 65/65/EEC" there is substituted "Directive 2001/83/EC of the European Parliament and of the Council on the Community code relating to medicinal products for human use".

Amendment of the Advisory Board on the Registration of Homoeopathic Products Order 1995

14. In the Medicines (Advisory Board on the Registration of Homoeopathic Products) Order 1995(**26**), in article 2(2) (conditions in respect of homoeopathic products in which the Advisory Board on the Registration of Homoeopathic Products was established to advise), in sub-paragraph (a) for "Article 2(1) of Council Directive 92/73/EEC" there is substituted "Directive 2001/83/EC of the European Parliament and of the Council on the Community code relating to medicinal products for human use".

Amendment of the Medical Devices (Consultation Requirements) (Fees) Regulations 1995

15. In the Medical Devices (Consultation Requirements) (Fees) Regulations 1995(**27**), regulation 1(2) (interpretation) is amended as follows—

(a) in the definition of "competent body" for "Council Directive 65/65/EEC" there is substituted "Directive 2001/83/EC of the European Parliament and of the Council on the Community code relating to medicinal products for human use"; and

(b) in the definition of "manufacturing authorisation" for "Article 16 of Council Directive 75/319/EEC" there is substituted "Article 40 of Directive 2001/83/EC of the European Parliament and of the Council on the Community code relating to medicinal products for human use"; and

(c) in the definition of "medicinal substance" for "Article 1 of Council Directive 65/65/EEC" there is substituted "Article 1 of Directive 2001/83/EC of the European Parliament and of the Council on the Community code relating to medicinal products for human use".

Amendment of the Fees Regulations 1995

16. The Medicines (Products for Human Use—Fees) Regulations 1995(**28**) are amended as follows—

(a) in regulation 2(1) (interpretation)—

(i) in the definition of "concerned member State" for "Chapter III of Directive 75/319/EEC" there is substituted "Title III, Chapter 4 of the 2001 Directive",

(ii) for the definition of "Directive 75/319/EEC" there is substituted the following definition—

""the 2001 Directive" means Directive 2001/83/EC of the European Parliament and of the Council on the Community code relating to medicinal products for human use;",

(iii) in the definition of "medicinal product" for "Chapters II to V of Council Directive 65/65/EEC apply" there is substituted "the 2001 Directive applies", and

(iv) for the definition of "Periodic Safety Update Report" there is substituted the following definition—

(**26**) S.I. 1995/309.
(**27**) S.I. 1995/449.
(**28**) S.I. 1995/1116; relevant amendments were made by S.I. 1998/574, 2000/592 and 3031, and 2001/795.

""Periodic Safety Update Report" means a report prepared to meet the requirements of the 2001 Directive and in accordance with the International Conference on Harmonisation and Committee on Proprietary Medicinal Products Guidance on clinical safety data management—Periodic Safety Update Reports for marketing drugs;";

(b) in regulation 6A (meaning of "set of applications")—

(i) for "Chapter III of Directive 75/319/EEC" there is substituted "Title III, Chapter 4 of the 2001 Directive", and

(ii) for "article 9.4 of Council Directive 75/319/EEC", in both places where those words occur, there is substituted "Article 28.4 of the 2001 Directive";

(c) in regulation 6B (application for regulatory assistance under the mutual recognition procedure) for "Chapter III of Directive 75/319/EEC" there is substituted "Title III, Chapter 4 of the 2001 Directive";

(d) in regulation 6C (time for payment of fees under regulation 4B) for "article 9.3 of Directive 75/319" there is substituted "Article 28.1 of the 2001 Directive";

(e) in Schedule 1, Part 1, paragraph 1 (interpretation)—

(i) in head (b) of the definition of "decentralised incoming application" for "Chapter III of Directive 75/319/EEC" there is substituted "Title III, Chapter 4 of the 2001 Directive", and

(ii) in head (a) of the definition of "simple application" for "Article 4.8(a)(i) of Council Directive 65/65/EEC" there is substituted "Article 10.1(a)(i) of the 2001 Directive";

(f) in Schedule 1, Part II, paragraph 1(1) (capital fees for marketing authorizations), in column 1 of the Table, entry 1 (major application) in head (a) for "Part 4 of the Annex to Council Directive 75/318/EEC" there is substituted "Part 4 of Annex I to the 2001 Directive";

(g) in Schedule 1, Part IIA, paragraph 2 (outgoing mutual recognition applications) for "Chapter III of Directive 75/319/EEC" there is substituted "Title III, Chapter 4 of the 2001 Directive";

(h) in Schedule 1, Part III (capital fees for applications for variations)—

(i) in paragraph 1, in head (b)(ii) of the definition of "Type II Complex Variation Application" for "Section H of Part IV of Annex to Council Directive 75/318/EEC" there is substituted "Section H of Part IV of Annex I to the 2001 Directive", and

(ii) in paragraphs 4 and 5 for "Section G of Part 4 of the Annex to Council Directive 75/318/EEC", in each place where those words occur, there is substituted "Section G of Part 4 of Annex I to the 2001 Directive";

(i) in Schedule 3, Part 1, paragraph 1 (periodic fees for licences—interpretation) in the definition of "limited use drug" for "Section G of Part 4 of the Annex to Council Directive 75/318/EEC" there is substituted "Section G of Part 4 of Annex I to the 2001 Directive";

(j) in Schedule 3, Part IV (types of marketing authorization for which only one periodic fee is payable), in paragraph 1 for "Council Directive 65/65/EEC" there is substituted "the 2001 Directive";

(k) in Schedule 4 (time for payment of capital fees—applications made by small companies), in paragraph 4A, sub-paragraphs (a)(i) and (b)(i) for "article 9.3 of Directive 75/319", in each place where those words occur, there is substituted "Article 28.1 of the 2001 Directive"; and

(l) in Schedule 5 (waiver, reduction or refund of capital fees), in paragraph 6 for "Council Directive 65/65/EEC" there is substituted "the 2001 Directive".

Amendment of the Health Service Medicines (Control of Prices of Branded Medicines) Regulations 2000 and the Health Service Medicines (Control of Prices of Generic Medicines) Regulations 2000

17. In both the Health Service Medicines (Control of Prices of Branded Medicines) Regulations 2000(**29**) and the Health Service Medicines (Control of Prices of Specified Generic Medicines) Regulations 2000(**30**), in regulation 2(1) (interpretation) for paragraph (a) of the definition of "marketing authorisation", in each of those instruments, there is substituted—

> "(a) by the competent authorities of the United Kingdom in accordance with the Directive 2001/83/EC of the European Parliament and of the Council on the Community code relating to medicinal products for human use;".

Amendment of the Stop Now Orders EC Directive Regulations 2001

18. In the Stop Now Orders (EC Directive) Regulations 2001(**31**), in Schedule 1 (meaning of "the Directives") for entry 6 there is substituted "Directive 2001/83/EC of the European Parliament and of the Council on the Community code relating to medicinal products for human use, in so far as it relates to the advertising of medicinal products for human use.".

Amendment of the Health Service Medicines (Information on Prices of Specified Generic Medicines) Regulations 2001

19. In the Health Service Medicines (Information on the Prices of Specified Generic Medicines) Regulations 2001(**32**), in regulation 2(1) (interpretation), in the definition of "marketing authorisation" for paragraph (a) there is substituted—

> "(a) by the competent authorities of the United Kingdom in accordance with Directive 2001/83/EC of the European Parliament and of the Council on the Community code relating to medicinal products for human use; or".

Signed by authority of the Secretary of State for Health

Hunt
Parliamentary Under Secretary of State,
Department of Health

7th February 2002

(**29**) S.I. 2000/123.
(**30**) S.I. 2000/1763.
(**31**) S.I. 2001/1422.
(**32**) S.I. 2001/3798.

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations make consequential amendments to the references in the Medicines Act 1968 and various statutory instruments relating to medicinal products and devices following the adoption of Directive 2001/83/EC of the European Parliament and of the Council on the Community code relating to medicinal products for human use. That Codification Directive repealed and re-enacted Council Directive 65/65/EEC (and its successive amendments, namely Council Directives 66/454/EEC, 75/319/EEC, 83/570/EEC, 87/21/EEC, 89/341/EEC, 92/27/EEC and 93/39/EEC); Council Directive 75/318/EEC (and its successive amendments, namely Council Directives 83/570/EEC, 87/19/EEC, 89/341/EEC, 91/507/EEC and 93/39/EEC and Commission Directives 1999/82/EC and 1999/83/EC); Council Directive 75/319/EEC (and its successive amendments, namely Council Directives 78/420/EEC, 83/570/EEC, 89/341/EEC, 92/27/EEC and 93/39/EEC and Commission Directive 2000/38/EC); Council Directive 89/342/EEC; Council Directive 89/343/EEC; Council Directive 89/381/EEC; Council Directive 92/25/EEC; Council Directive 92/26/EEC; Council Directive 92/27/EEC; Council Directive 92/28/EEC and Council Directive 92/73/EEC. Where references to the repealed Directives appeared in the Medicines Act 1968 and statutory instruments numbered 1971/972, 1971/974, 1976/1726, 1992/3146, 1993/2538, 1994/105, 1994/1932, 1994/1933, 1994/2987, 1994/3017, 1994/3144, 1995/309, 1995/449, 1995/1116, 2000/123, 2000/1763, 2001/1422 and 2001/3798, they have been replaced with an appropriate reference to the 2001 Codification Directive and related legislation.

In addition, these Regulations implement Commission Directive 2000/38/EC of 5th June 2000 amending Chapter Va (Pharmacovigilance) of Council Directive 75/319/EEC on the approximation of provisions laid down by law, regulation or administrative action relating to medicinal products. That implementation is effected by adding a new sub-paragraph (d) to paragraph 10 of Schedule 3 to the Medicines for Human Use (Marketing Authorisations Etc.) Regulations 1994 and importing the amendments made by Commission Directive 2000/38/EC into the amended definition of "the relevant Community provisions" which appears in those Regulations. For the purposes of the implementation, that definition is relevant in particular in regulation 7 of those Regulations (obligations of holders of marketing authorisations and offences).

A Regulatory Impact Assessment in relation to these Regulations, and a Transposition Note in relation to the implementation of Commission Directive 2000/38/EC, have been placed in the libraries of both Houses of Parliament and copies may be obtained from the Medicines Control Agency, Market Towers, 1 Nine Elms Lane, London SW8 5NQ.