STATUTORY INSTRUMENTS

1977 No. 996

MEDICINES

The Medicines (Labelling) Amendment Regulations 1977

Made - - - -	*2nd June* 1977
Laid before Parliament	*10th June* 1977
Coming into Operation	*1st July* 1977

The Secretaries of State respectively concerned with health in England and in Wales, the Secretary of State concerned with health and with agriculture 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 powers conferred by sections 85(1), 85(4) and 91(2) and (3) of the Medicines Act 1968(a) and now vested in them (b) 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 the following regulations, hereby make the following regulations:—

Citation and interpretation

1. These regulations, which may be cited as the Medicines (Labelling) Amendment Regulations 1977, shall be read as one with the Medicines (Labelling) Regulations 1976(c) (hereinafter referred to as "the principal regulations").

Commencement

2. These regulations shall come into operation on 1st July 1977 and in the case of regulations 9 and 10 shall, subject to the provisions of regulation 19 of the principal regulations (temporary provisions), have effect—

(*a*) in relation to a dispensed medicinal product, on 1st July 1977 in the case of regulation 9 and on 1st July 1979 in the case of regulation 10;

(a) 1968 c. 67.

(b) 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 (1969 I, p. 1070)), and 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).

(c) S.I. 1976/1726 (1976 III, p. 4570).

(*b*) in relation to a medicinal product to which—

(i) a product licence, clinical trial certificate or animal test certificate relates which is granted or issued on or after 1st July 1977, or

(ii) a product licence which has been granted before 1st July 1977 relates, any of the provisions of which relating to the composition of the medicinal product, or particulars as to the uses and effect of, or warnings concerning, the product, are varied on or after 1st July 1977, except where the provisions of the product licence, as so varied, include a provision that labelling on containers and packages of the product may continue to be used after the date on which the provisions of the licence are so varied,

on the date on which such licence or certificate is granted or issued or the provisions of such licence are varied, as the case may be;

(*c*) in relation to a medicinal product, not being a medicinal product to which the provisions of paragraphs (*a*), (*b*), (*d*) or (*e*) of this regulation apply, on 1st January 1978;

(*d*) in relation to a medicinal product to which a product licence which is a licence of right relates, or a medicinal product in such a container as is mentioned in paragraph (3) or (4) of regulation 5 of the principal regulations (small containers, wrappers or sealed units), not, in either case, being a medicinal product to which the provisions of paragraph (*a*) or (*b*) of this regulation apply—

(i) where such medicinal product is assembled in the same labelled container in which the product is to be sold by retail or supplied in circumstances corresponding to retail sale, on 1st July 1979, or

(ii) where such medicinal product is not such a product as is mentioned in the preceding sub-paragraph, on 1st July 1980;

(*e*) in relation to such a medicinal product as is mentioned in regulation 14 of the principal regulations (medicinal products for incorporation in animal feeding stuffs), on 1st January 1978,

and, in the case of paragraph (2) of regulation 13 and paragraph (1) of regulation 14 shall, subject to the provisions of regulation 19 of the principal regulations, have effect—

(*f*) in relation to a medicinal product which is assembled in the same labelled container in which the product is to be sold or supplied in circumstances corresponding to retail sale, on 1st July 1979, or

(*g*) in relation to a medicinal product which is not such a product as is mentioned in sub-paragraph (*f*) above, on 1st July 1980.

Amendment of regulation 2 of the principal regulations

3.—(1) Regulation 2 of the principal regulations (commencement) shall be amended in accordance with the following paragraphs of this regulation.

(2) In paragraph (*c*), for the words "1st July 1977" there shall be substituted the words "1st January 1978".

(3) In paragraph (*d*), for the words "1st January 1979" there shall be substituted the words "1st July 1979" and for the words "1st January 1980" there shall be substituted the words "1st July 1980".

(4) In paragraph (*e*), for the words "1st July 1977" there shall be substituted the words "1st January 1978".

Amendment of regulation 3 *of the principal regulations*

4. In regulation 3(1) of the principal regulations (definitions)—

(*a*) immediately after the definition of "appropriate non-proprietary name", for the words "appropriate quantitive particulars" there shall be substituted the words "appropriate quantitative particulars" and in paragraph (iv) of the said definition of "appropriate quantitative particulars" the word "active" shall be omitted in the second place where it occurs;

(*b*) for the definition of "expiry date" there shall be substituted the definition—

" "expiry date" means the date after which, or the month and year after the end of which, the medicinal product should not be used, or the date before which, or the month and year before the beginning of which, the medicinal product should be used;";

(*c*) immediately after the definition of "medicinal product" there shall be inserted the definition—

" "medicinal product on a general sale list" has the same meaning as in section 51(2) of the Act;";

(*d*) in the definition of "unit preparation", for the words "inert liquid diluent" there shall be substituted the words "inert diluent" and for the words "in liquid form or" there shall be substituted the words "in this diluted form or, where applicable,".

Amendment of regulation 9 *of the principal regulations*

5.—(1) Regulation 9 of the principal regulations (dispensed medicinal products) shall be amended in accordance with the following paragraphs of this regulation.

(2) After paragraph (2) there shall be inserted the following two paragraphs:—

"(3) Where a number of containers or packages, or of containers and packages, of dispensed medicinal products all of the same description are enclosed in a package, paragraph (1)(*f*) of this regulation shall be deemed to have been complied with if such of the particulars referred to in that paragraph as would, apart from this paragraph, be required to be shown on each container or package, or on each container and package so enclosed are shown either on one or more of such containers or packages or on the package which immediately encloses such containers or packages or such containers and packages as the case may be.

(4) Where a medicinal product is a dispensed medicinal product by reason only of its being a medicinal product falling within the definitions in sub-paragraphs (iv) or (v) of the definition of "dispensed medicinal product" in paragraph (1) of regulation 3 of these regulations, the container or package of such product shall not be required to be labelled in accordance with the provisions of this regulation if and so long as such container or package is labelled in accordance with the provisions of regulation 5 of these regulations.".

Amendment of regulation 12 *of the principal regulations*

6. In regulation 12(1)(*b*) of the principal regulations (importation and exportation), for the words "any medicinal product, not being a biological substance," there shall be substituted the words "any other medicinal product".

Amendment of regulation 13 *of the principal regulations*

7. In regulation 13 of the principal regulations (delivery and storage), for the words "a number of packages of medicinal products" there shall be substituted the words "a number of containers or packages, or of containers and packages, of medicinal products all".

Amendment of regulation 14 *of the principal regulations*

8. In regulation 14(4) of the principal regulations (medicinal products for incorporation in animal feeding stuffs), the words "12 and" shall be omitted.

Additional regulations

9.—(1) Immediately after regulation 14 of the principal regulations there shall be inserted the following five regulations:—

"*Medicinal products on a general sale list*

14A.—(1) Subject to the following provisions of these regulations, where a medicinal product on a general sale list, not being a dispensed medicinal product, is sold by retail, or supplied in circumstances corresponding to retail sale or by means of an automatic machine or is in the possession of any person for the purpose of such sale or supply, every container and every package immediately enclosing a container of such product, being a product described in any of the numbered paragraphs of Schedule 5 to these regulations, shall be labelled to show the words and particulars set out in such paragraph or paragraphs.

(2) Where a container or package is required by this regulation to show:—

(*a*) words set out in more than one of the paragraphs numbered 2, 3 and 4 of the said Schedule 5, there may be substituted for those words other words showing that the product contains more than one of the substances aloxiprin, aspirin and paracetamol and naming the said substances so contained, except that in the case of aloxiprin, the words "aspirin derivative" shall appear and the word "aloxiprin" need not appear;

(*b*) words set out in one or more of the paragraphs numbered 6, 7 and 8 of the said Schedule 5 or referred to in paragraph (2)(*a*) above, such words shall appear in a prominent position and shall be within a rectangle within which there shall be no other matter of any kind, except that where words set out in more than one of the said paragraphs appear on the container or package then any of them may together be within a rectangle within which there shall be no other matter of any kind.

(3) Where a container or package is required to be labelled to show the words "Do not exceed the stated dose", such words shall appear adjacent to

either the directions for use, where such directions appear on the container or package, or the recommended dosage, where such recommendation appears on the container or package.

(4) Where a container or package is required to be labelled to show the words "Do not exceed the stated dose", such words shall not be required to be shown if, by virtue of regulation 14B of these regulations, the words set out in paragraph 1 of Schedule 6 to these regulations are required to be, and are, shown.

Medicinal products not on a general sale list

14B.—(1) Subject to the following provisions of these regulations, where a medicinal product to which any of the restrictions imposed by section 52 of the Act (sale or supply of medicinal products not on general sale list) apply is sold by retail, or supplied in circumstances corresponding to retail sale or is offered or exposed for sale by retail, every container and every package immediately enclosing a container of such product—

(*a*) shall be labelled in accordance with the provisions of regulation 14A of these regulations as if such provisions applied to such containers and packages as they apply to containers and packages of medicinal products on a general sale list;

(*b*) shall, if the product is described in any of the numbered paragraphs of Schedule 6 to these regulations, be labelled to show the words and particulars set out in such paragraph or paragraphs, except that where words set out in more than one of the paragraphs numbered 1, 2 and 3 of the said Schedule 6 appear on the container or package then the word "Warning" need not appear more than once and where the product is a dispensed medicinal product then the words set out in paragraphs 1, 2 and 3 of the said Schedule 6 need not appear.

(*c*) shall, unless any of the provisions of regulation 14C of these regulations apply to such container or package or the product is a dispensed medicinal product, be labelled to show the capital letter "P" within a rectangle within which there shall be no other matter of any kind.

(2) The requirement of paragraph (1)(*c*) above shall apply to every container and every package immediately enclosing a container of a medicinal product which is sold by way of wholesale dealing and which is not a medicinal product on a general sale list.

(3) Where a container or package is required by this regulation to be labelled to show any of the words or particulars contained in the said Schedule 6, such words or particulars shall be within a rectangle within which there shall be no other matter of any kind, except that where words or particulars set out in more than one numbered paragraph of the said Schedule 6 appear on the container or package then any of them may together be within a rectangle within which there shall be no other matter of any kind.

Prescription only medicines

14C. Subject to the following provisions of these regulations, every container and every package immediately enclosing a container of a medicinal product falling within a description or class specified in any order made under section 58(1) of the Act (medicinal products on prescription only)

subsequent to the coming into operation of these regulations and for the time being in force shall, if the product is described in paragraph 4, 5, 6 or 7 of Schedule 6 to these regulations, be labelled to show the words and particulars set out in such paragraph or paragraphs, as the case may be, and shall, except where the product is sold by retail or supplied in circumstances corresponding to retail sale or is the subject of an exemption, by virtue of the provisions of section 58(4)(*a*), from any of the restrictions imposed by section 58(2) of the Act, be labelled to show the letters "POM" in capital letters within a rectangle within which there shall be no other matter of any kind.

Veterinary drugs

14D. Subject to the following provisions of these regulations, where a medicinal product (not being a dispensed medicinal product) is a veterinary drug to which a licence granted under Part II of the Act applies and the said licence either does not extend to Northern Ireland or applies to Northern Ireland only, every container and every package immediately enclosing a container of such product shall be labelled to show that the product is for sale or supply in Great Britain only or in Northern Ireland only as the case may be.

Small containers, wrappers and sealed units

14E.—(1) Subject to paragraph (3) of this regulation, where the container of a medicinal product is an ampoule or other container of not more than 10 millilitres nominal capacity which is immediately enclosed in a package which is labelled in accordance with those provisions of regulations 14A to 14C of these regulations which apply to such package, the provisions of those regulations shall not apply to such container.

(2) Subject to paragraph (3) of this regulation, where the container is in the form of a wrapper consisting of paper, film, plastic material, metal foil or other sheet or strip material or in the form of a bubble, blister or other sealed unit consisting of such sheet or strip material, enclosing one or more dosage units of a medicinal product and such container is immediately enclosed in a package which is labelled in accordance with those provisions of regulations 14A to 14D of these regulations which apply to such package, the provisions of those regulations shall not apply to such container.

(3) Subject to the following provisions of these regulations, where the package immediately enclosing such a container as is described in paragraph (2) above is itself in the form of a bubble, blister or other sealed unit as is mentioned in that paragraph and is part of a continuous series comprising a sheet or strip of like packages and is required to be labelled to show any of the words, particulars or letters contained or referred to in regulations 14A to 14D of these regulations, such requirements shall be deemed to have been complied with if the said words, particulars or letters, as the case may be, are displayed at frequent intervals on the said sheet or strip of such packages.".

(2) After Schedule 4 to the principal regulations there shall be added as Schedules 5 and 6 the Schedules set out in the Schedule to these regulations.

Amendment of regulation 17 *of the principal regulations*

10. In regulation 17 of the principal regulations (general provisions), imme-

diately after paragraph (6) there shall be inserted the following paragraph:—

"(6A) Where a medicinal product is sold by retail, or supplied in circumstances corresponding to retail sale or by means of an automatic machine, every container and every package immediately enclosing a container of such product shall be labelled to show the words "Keep out of the reach of children" or other sufficient words of direction bearing a similar meaning, except that this paragraph shall not apply to—

(i) a container or a package of a medicinal product which falls or would, were it for sale or to be for sale in the circumstances set out in Article 2(1) of the Medicines (Exemption from Licences) (Foods and Cosmetics) Order 1971**(a)** as amended **(b)**, fall within any of the exemptions conferred by that order as so amended, or

(ii) a container or a package of a medicinal product which is on a general sale list and is a toothpaste, or

(iii) a container or a package of a medicinal product which is on a general sale list and which is for sale as confectionery and which is not or is not to be sold with, accompanied by or having in relation to it, any particulars in writing specifying that product's curative or remedial function, or the use of that product for such curative or remedial purposes, in relation to a disease specified other than coughs, colds or nasal congestion, or

(iv) such a container of a medicinal product as is described in paragraph (3) or (4) of regulation 5 of these regulations (small containers, wrappers or sealed units), or

(v) a package immediately enclosing such a container as is mentioned in paragraph (4) of regulation 5 of these regulations, if such package is itself in the form of a bubble, blister or other sealed unit as is mentioned in that paragraph and is enclosed in a package.".

Amendment of regulation 18 *of the principal regulations*

11. In regulation 18(2)(ii) of the principal regulations (miscellaneous provisions), the words "(not being a package to which the provisions of regulation 13 of these regulations are applicable)" shall be omitted.

Amendment of regulation 19 *of the principal regulations*

12.—(1) Regulation 19 of the principal regulations (temporary provisions) shall be amended in accordance with the following paragraphs of this regulation.

(2) In paragraph (1)(*a*), for the words "30th June 1978" there shall be substituted the words "31st December 1978".

(3) In paragraph (1)(*b*), for the words "1st July 1977" there shall be substituted the words "1st January 1978" and for the words "30th June 1978" there shall be substituted the words "31st December 1978".

(4) In paragraph (1)(*c*), for the words "31st December 1977" there shall be substituted the words "30th June 1978" and for the words "31st December 1978" there shall be substituted the words "30th June 1979".

(a) S.I. 1971/1410 (1971 II, p. 3945). **(b)** S.I. 1973/2079 (1973 III, p. 7182).

(5) In paragraph (1)(*d*), for the words "31st December 1978" there shall be substituted the words "30th June 1979" and for the words "31st December 1979" there shall be substituted the words "30th June 1980".

(6) At the end of paragraph (1)(*d*) there shall be inserted the following sub-paragraph:—

"(*e*) where a person who has manufactured such a medicinal product in the course of a business carried on by him sells such a medicinal product or has in his possession such product for sale in such circumstances as to comply with all requirements as to labelling which applied to that product at any time during the period between the coming into operation of these regulations and 1st July 1977, and—

(i) the container of such a medicinal product is labelled by means of a label affixed to the container and that label was printed before 1st July 1977 or the package of such medicinal product was printed before that date, or

(ii) the container of such a medicinal product is labelled by means of fired on, embossed or similar labelling applied to the body of the container before 1st October 1977,

and the container or the package is labelled to comply with the requirements set out in sub-paragraph (*a*) above, during the period until and including 31st December 1978, for the purposes of the application of these regulations in relation to such sale or possession, the requirements of these regulations shall be regarded as having been complied with.".

(7) In paragraph (2), for the words "1st July 1977" there shall be substituted the words "1st January 1978", for the words "30th June 1979" the words "31st December 1979" and for the words "30th June 1980" the words "31st December 1980".

(8) In paragraphs (1)(*b*) and (*c*) and (2)(*b*) immediately after the word "sells" in each place where it occurs there shall be inserted the words "or supplies", immediately after the words "for sale" in each place where they occur there shall be inserted the words "or supply" and for the words "sale or possession" in each place where they occur there shall be substituted the words "sale, supply or possession".

(9) In paragraph (2)(*a*), there shall be omitted the word "such" in the third place where it occurs and there shall also be omitted the words "as is mentioned in paragraph (3) or (4) of regulation 5 of these regulations (small containers, wrappers or sealed units)".

Amendment of Schedule 1 to the principal regulations

13.—(1) In paragraph 1(*e*) of Schedule 1 to the principal regulations (standard particulars required in the labelling of containers and packages), for the words "except that where any ingredient" there shall be substituted the words "except that where any medicinal product or ingredient" and for the words "the quantity of that ingredient" there shall be substituted the words "the quantity of that product or ingredient".

(2) In paragraph 1(*d*) of that Schedule, there shall be omitted the words "except where such specified publication is the current edition of the British Pharmacopoeia or the British Pharmaceutical Codex".

(3) For paragraph 3 of that Schedule, there shall be substituted the following paragraph:—

"3. Directions for use and, where the medicinal product is for use by being administered to animals, the purposes for which the medicinal product is to be used, except that where—

(*a*) it is a provision of the product licence which relates to the medicinal product that the product may not be sold or supplied except by an appropriate practitioner or in accordance with a prescription given by a practitioner, or

(*b*) the medicinal product is a product which is specified in an order made under section 58(1) of the Act (medicinal products on prescription only), or

(*c*) the medicinal product is not assembled in the same labelled container in which the product is to be sold by retail or supplied in circumstances corresponding to retail sale,

such directions for use may be shown by a statement that the medicinal product is to be used in accordance with the directions of an appropriate practitioner.".

(4) At the end of paragraph 9 of that Schedule there shall be inserted the words "except that there may be omitted from such product licence number any figure which is part of the identification of the holder of the licence to which the product licence number relates, if such figure is the figure 0 and is not preceded by any figure, being part of such identification, other than the figure 0".

Amendment of Schedule 4 *to the principal regulations*

14.—(1) In paragraph 3 of Schedule 4 to the principal regulations (particulars required in the labelling of containers and packages of medicinal products for incorporation in animal feeding stuffs or which are medicated animal feeding stuffs), there shall be omitted the words "except where such specified publication is the current edition of the British Pharmacopoeia or the British Pharmaceutical Codex,".

(2) Paragraph 12 of that Schedule shall be omitted.

(3) At the end of paragraph 14 of that Schedule there shall be inserted the words "except that there may be omitted from such product licence number any figure which is part of the identification of the holder of the licence to which the product licence number relates, if such figure is the figure 0 and is not preceded by any figure, being part of such identification, other than the figure 0".

David Ennals,
Secretary of State for Social Services.

20th May 1977.

John Morris,
Secretary of State for Wales.

23rd May 1977.

Bruce Millan,
Secretary of State for Scotland.

30th May 1977.

In witness whereof the official seal of the Minister of Agriculture, Fisheries and Food is hereunto affixed on 31st May 1977.

(L.S.)

John Silkin,
Minister of Agriculture, Fisheries and Food.

Sealed with the official seal of the Department of Health and Social Services for Northern Ireland this 1st day of June 1977.

(L.S.)

J. H. Copeland,
Deputy Secretary.

Sealed with the official seal of the Department of Agriculture for Northern Ireland this 2nd day of June 1977.

(L.S.)

J. A. Young,
Permanent Secretary.

SCHEDULE Regulation 9(2)

SCHEDULES ADDED TO THE PRINCIPAL REGULATIONS

SCHEDULE 5 Regulation 14A

WORDS AND PARTICULARS REQUIRED IN THE LABELLING OF CONTAINERS AND PACKAGES OF MEDICINAL PRODUCTS ON A GENERAL SALE LIST

1. If the product is for administration to human beings and contains aloxiprin, aspirin or paracetamol, the words "If symptoms persist, consult your doctor" and the recommended dosage, except where the product is for external use only.

2. If the product is for administration to human beings and contains aloxiprin, the words "Contains an aspirin derivative".

3. If the product is for administration to human beings and contains aspirin, the words "Contains aspirin", except where the product is for external use only or where the name of the product appears on the container or package, as the case may be, and includes the word "aspirin".

4. If the product is for administration to human beings and contains paracetamol, the words "Contains paracetamol", except where the name of the product appears on the container or package, as the case may be, and includes the word "paracetamol".

5. If the product is for administration to human beings and contains paracetamol, the words "Do not exceed the stated dose".

6. If the product is a veterinary drug and contains aloxiprin, the words "Unsuitable for cats" and "Contains an aspirin derivative".

7. If the product is a veterinary drug and contains aspirin, the words "Unsuitable for cats" and, except where the name of the product appears on the container or package, as the case may be, and includes the word "aspirin", the words "Contains aspirin".

8. If the product is a veterinary drug and contains salicylamide, the words "Unsuitable for cats".

SCHEDULE 6 Regulation 14B

WORDS AND PARTICULARS REQUIRED IN THE LABELLING OF CONTAINERS AND PACKAGES OF MEDICINAL PRODUCTS TO WHICH SECTION 52 OF THE ACT APPLIES

1. If the product, being for administration to human beings, falls within a description or class to which any of the restrictions imposed by section 58 of the Act apply by virtue of any order made under that section subsequent to the coming into force of these regulations and for the time being in force but for an exemption from any such restrictions conferred by such an order by reason of the proportion or level in such product of any substance, the words "Warning. Do not exceed the stated dose", except where the product is for external use only or contains any of the substances described in paragraph 3 of this Schedule.

2. If the product is for administration to human beings and either is for the treatment of asthma or other conditions associated with bronchial spasm or contains ephedrine or any of its salts, the words "Warning. Asthmatics should consult their doctor before using this product", except where the product is for external use only.

3. If the product is for administration to human beings and contains any of the following antihistaminic and other substances or any of their salts or molecular compounds, namely antazoline, bamipine, bromodiphenhydramine, bromphenir-

amine, buclizine, carbinoxamine, chlorcyclizine, chlorpheniramine, cinnarizine, clemastine, clemizole, cyclizine, cyproheptadine, dimenhydrinate, dimethindene, diphenhydramine, diphenylpyraline, doxylamine, embramine, hyoscine, isothipendyl, mebhydrolin, meclozine, mepyramine, methapyrilene, phenindamine, pheniramine, phenyltoloxamine, promethazine, pyrrobutamine, thenyldiamine, tripelennamine and triprolidine, the words "Warning. May cause drowsiness. If affected do not drive or operate machinery. Avoid alcoholic drink", except where the product is for external use only.

4. If the product is embrocation, liniment, lotion, liquid antiseptic or other liquid preparation or gel and is for external use only, the words "For external use only".

5. If the product is for administration to human beings and contains hexachlorophane, either the words "Not to be used for babies" or a warning that the product is not to be administered, except on medical advice, to a child under two years.

6. If the product is a veterinary drug containing hexachlorophane and is for oral administration for the prevention or treatment of liver fluke disease in cattle, a warning that the product is not for use in lactating cattle.

7. If the product is a veterinary drug containing hexachlorophane and is for oral administration for the prevention or treatment of liver fluke disease in sheep or cattle, a warning that protective clothing must be worn by the operator when the product is being administered.

EXPLANATORY NOTE

(This Note does not form part of the Regulations.)

These Regulations amend the Medicines (Labelling) Regulations 1976. The main changes are—

(*a*) in the principal regulations, the dates specified in regulations 2(*c*), (*d*) and (*e*) and 19 (except 19(1)(*b*)(i)) are postponed by six months;

(*b*) a new regulation 17(6A) is added requiring containers and packages of medicinal products (with some exceptions) to be labelled to show the words "Keep out of the reach of children" or a permitted variant thereof;

(*c*) new regulations 14A to 14D and new Schedules 5 and 6 are added containing labelling requirements for certain categories of medicinal products;

(*d*) a new regulation 14E is added containing exemptions from and modifications of the new regulations 14A to 14D in the case of small containers, wrappers and sealed units.

The other amendments are of a minor nature.

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