STATUTORY INSTRUMENTS

1978 No. 40

MEDICINES

The Medicines (Fluted Bottles) Regulations 1978

Made - - - -	*16th January 1978*
Laid before Parliament	*17th January 1978*
Coming into Operation	*1st February 1978*

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 87(1) and 91(2) and (3) and section 129(5) of the Medicines Act 1968 and now vested in them(**1**) 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 regulations, hereby make the following regulations:—

Citation, commencement and interpretation

1.—(1) These regulations may be cited as the Medicines (Fluted Bottles) Regulations 1978 and shall come into operation on 1st February 1978.

(2) In these regulations—

"the Act" means the Medicines Act 1968;

"external use" means—

(a) in relation to medicinal products for use by being administered to human beings, application to the skin, teeth, mucosa of the mouth, throat, nose, ear, eye, vagina or anal canal but does not include the use of throat sprays, nasal drops, nasal sprays, nasal inhalations, teething preparations or dental gels;

(b) in relation to medicinal products for use by being administered to animals, application to the skin, hair, fur, feathers, scales, hoof, horn, ear, eye, mouth, mucosa of the throat, or prepuce;

and other expressions have the same meanings as in the Act.

(**1**) 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).

(3) Except in so far as the context otherwise requires, any reference in these regulations to any provision of any enactment or instrument shall be construed as a reference to that provision as amended or extended by any enactment or instrument and as including a reference to any provision which may re-enact or replace it.

(4) The rules for the construction of Acts of Parliament contained in the Interpretation Act 1889 shall apply for the purposes of the interpretation of these regulations as they apply for the purposes of an Act of Parliament.

Requirements for containers of certain medicinal products

2. Subject to the provisions of these regulations, and for the purposes of promoting safety in relation to medicinal products and securing that medicinal products are readily identifiable, the sale or supply of liquid medicinal products for external use containing or consisting of any substance set out in the Schedule to these regulations shall be prohibited unless such products are contained in a bottle the outer surface of which is fluted vertically with ribs or grooves recognisable by touch.

Exceptions

3. The prohibition imposed by regulation 2 above shall not apply in the following circumstances—

(a) where medicinal products are contained in bottles with a capacity greater than 1.14 litres;

(b) where a medicinal product is sold or supplied and an exception is specified in column 2 of the Schedule to these regulations in relation to a medicinal product containing or consisting of a substance specified in column 1 of such Schedule;

(c) where a substance specified in column 1 of the Schedule to these regulations is contained in a medicinal product which is of a description or falling within a class specified in any order made under section 58(1) of the Act (medicinal products on prescription only), unless sold or supplied by retail sale or in accordance with a prescription given by a practitioner;

(d) where medicinal products for use solely outside the United Kingdom are placed in containers for the purpose of export;

(e) where medicinal products are sold or supplied solely for the purpose of scientific education, research or analysis;

(f) where eye or ear drops are sold or supplied in a plastic container; or

(g) where a product licence, clinical trial certificate or animal test certificate, or any variation of any such licence or certificate, enables medicinal products to be contained in a bottle otherwise than in accordance with the requirements set out in regulation 2 above.

Offences

4. Any person who contravenes these regulations or who contravenes the provisions of section 87(2) of the Act shall be guilty of an offence and—

(a) shall be liable on summary conviction to a fine not exceeding £400, and

(b) shall be liable on conviction on indictment to a fine or to imprisonment for a term not exceeding two years or to both.

David Ennals
3rd January 1978 Secretary of State for Social Services

John Morris
10th January 1978 Secretary of State for Wales

Bruce Millan
10th January 1978 Secretary of State for Scotland

In witness whereof the official seal of the Minister of Agriculture, Fisheries and Food is hereunto affixed on 11th January 1978.

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 13th day of January 1978.

N. Dugdale
Permanent Secretary

Sealed with the official seal of the Department of Agriculture for Northern Ireland this 16th day of January 1978.

J. A. Young
Permanent Secretary

SCHEDULE

Regulations 2 and 3

Substance	*Circumstances exempting from the requirements to contain medicinal products in a fluted bottle*
1. Aconite, alkaloids of.	
2. Adrenaline; its salts.	
3. Amino-alcohols esterified with benzoic acid, phenylacetic acid, phenylpropionic acid, cinnamic acid or the derivatives of these acids; their salts.	
4. *p*-Aminobenzenesulphonamide; its salts; derivatives of *p*-aminobenzene sulphonamide having any of the hydrogen atoms of the *p*-amino group or of the sulphonamide group substituted by another radical; their salts.	
5. *p*-Aminobenzoic acid; esters of; their salts.	
6. Ammonia—	medicinal products containing less than 5 per cent. weight in weight of ammonia.
7. Arsenical substances, the following— Arsenic Sulphides Arsenates Arsenites Halides of Arsenic Oxides of Arsenic Organic Compounds of Arsenic.	
8. Atropine; its salts.	
9. Cantharidin; cantharidates.	
10. Carbachol.	
11. Chloral; its addition and its condensation products other than alphachloralose; their molecular compounds.	
12. Chloroform—	medicinal products containing less than 1 per cent. volume in volume of chloroform.
13. Cocaine; its salts.	
14. Creosote obtained from wood—	medicinal products containing less than 50 per cent. volume in volume of creosote obtained from wood.
15. Croton, oil of.	
16. Demecarium Bromide.	
17. Dyflos.	
18. Ecothiopate Iodide.	

Substance	*Circumstances exempting from the requirements to contain medicinal products in a fluted bottle*
19. Ephedrine; its salts—	medicinal products containing less than the equivalent of 1 per cent. weight in volume of ephedrine.
20. Ethylmorphine; its salts.	
21. Homatropine; its salts.	
22. Hydrofluoric acid; alkali metal bifluorides; potassium fluoride; sodium fluoride; sodium silicofluoride.	mouth washes containing not more than 0.05 per cent. weight in volume of sodium fluoride.
23. Hyoscine; its salts.	
24. Hyoscyamine; its salts.	
25. Lead Acetates—	medicinal products containing lead acetates equivalent to not more than 2.2 per cent. weight in volume of lead calculated as elemental lead.
26. Mercury, oxides of; nitrates of mercury; mercuric ammonium chloride; mercuric chloride; mercuric iodide; potassium mercuric iodide; organic compounds of mercury; mercuric oxycyanide; mercuric thiocyanate.	medicinal products containing not more than 0.01 per cent. weight in volume of phenyl mercuric salts or 0.01 per cent. weight in volume of sodium ethyl mercurithiosalicylate as a preservative.
27. Nitric Acid—	medicinal products containing less than 9 per cent. weight in weight of nitric acid.
28. Opium.	
29. Phenols (any member of the series of phenols of which the first member is phenol and of which the molecular composition varies from member to member by one atom of carbon and two atoms of hydrogen); compounds of phenol with a metal.	(*a*) medicinal products containing one or more of the following:— Butylated hydroxytoluene. Carvacrol. Creosote obtained from coal tar. Essential oils in which phenols occur naturally. Tar (coal or wood), crude or refined. *tert*-Butylcresol. *p-tert*-Butylphenol. *p-tert*-Pentylphenol. *p*-(1,1,3,3-tetramethylbutyl) phenol. Thymol. (*b*) mouth washes containing less than 2.5 per cent. weight in volume of phenols. (*c*) any liquid disinfectants or antiseptics not containing phenol and containing less than 2.5 per cent. weight in volume of other phenols.

Substance	*Circumstances exempting from the requirements to contain medicinal products in a fluted bottle*
	(*d*) other medicinal products containing less than 1 per cent. weight in volume of phenols.
30. Physostigmine; its salts.	
31. Picric Acid—	medicinal products containing less than 5 per cent. weight in volume of picric acid.
32. Pilocarpine; its salts.	medicinal products containing less than the equivalent of 0.025 per cent. weight in volume of pilocarpine.
33. Podophyllum Resin—	medicinal products containing not more than 1.5 per cent. weight in weight of podophyllum resin.
34. Solanaceous alkaloids not otherwise included in this Schedule.	

EXPLANATORY NOTE

These Regulations made under the Medicines Act 1968 impose a prohibition upon the sale or supply of certain medicinal products for external use except in bottles which are recognisable by touch. The Regulations, which contain exceptions and criminal offences, are made for the purpose of promoting safety in, and ready identification of, medicinal products. They supersede Rule 26 of the Poisons Rules.