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1988
Addendum 1989**

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British Pharmacopœia 1988

Addendum 1989

Notices

The General Notices and Appendices included in the British Pharmacopœia 1988 apply to all matter contained in this Addendum unless the contrary is specifically stated.

The Addendum has the same authority as the British Pharmacopœia 1988. Monographs and Appendices of the British Pharmacopœia 1988 that are amended by this Addendum supersede, in their amended forms, the original monographs and appendices.

Monographs of the European Pharmacopœia are distinguished by a five-pointed star against the title.

Patents

In this Addendum certain drugs and preparations have been included notwithstanding the existence of actual or potential patent rights. In so far as such substances are protected by Letters Patent their inclusion in this Addendum neither conveys, nor implies, licence to manufacture.

Effective Dates

Much of the material in this volume enters into force on 1 July 1989 but certain material that has been published earlier by Gazette Notices became effective on the date stated at the foot of the relevant entry.

Preface

This Addendum adds new material to and amends the British Pharmacopœia 1988. It is published by Her Majesty's Stationery Office for the Health Ministers on the recommendation of the Medicines Commission in accordance with section 99(6) of the Medicines Act 1968.

The Medicines Commission wishes to record its deep regret at the death of Dr C A Johnson CBE, lately Secretary and Scientific Director of the British Pharmacopœia Commission, who had retired in January 1988 after twenty-five years of distinguished service.

The Medicines Commission also expresses its appreciation to all who have contributed to the preparation of this Addendum.

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* Term of office ends 31 December 1991.

† Term of office ends 31 December 1989.

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Introduction

The British Pharmacopœia Commission intends that Addenda to the British Pharmacopœia 1988 should generally be produced every 12 to 18 months as was the practice with the first three addenda to the British Pharmacopœia 1980. This will facilitate the rapid revision of monographs and other texts in the light of developments in pharmaceutical production and quality control. In addition, the regular updating should help to ensure that the British Pharmacopœia will always include the current versions of all monographs of the European Pharmacopœia, edited into the style of the British Pharmacopœia for the convenience of users of the British Pharmacopœia.

The numbering of the pages in this Addendum is consecutive with that of the British Pharmacopœia 1988. The index is cumulative and it contains references to all material published in the British Pharmacopœia 1988 and the Addendum 1989. In general the effective date of this Addendum is 1 July 1989 but a number of items, particularly edited versions of European Pharmacopœia monographs, have already been, or will be, brought into effect at some other date. Where the effective date is not 1 July 1989, this is noted at the foot of the entry by means of an italicised statement of the month and year. Where no such statement appears it is to be understood that the effective date is that of the Addendum as a whole. With the bringing into effect of this Addendum, the British Pharmacopœia 1988 will comprise Volume I, Volume II and the Addendum 1989. It should be noted that material in Amendments Nos 1 and 2 to the British Pharmacopœia 1988 has been incorporated in this Addendum.

Some Additions

Monographs included in the Pharmacopœia for the first time include the corticosteroid Dexamethasone Acetate, Pizotifen Malate, which is used for the prophylaxis of migraine, Ascorbic Acid Injection, Menadiol Phosphate Injection, Procyclidine Injection, Nitrazepam Oral Suspension, Pizotifen Tablets and Pseudoephedrine Tablets.

Bacterial Endotoxins

A test for bacterial endotoxins has been introduced. The text, included as Appendix XIV O, is an edited version of that now published in the European Pharmacopœia. The method for the detection of Gram-negative endotoxins is based on the gelation of a lysate of amoebocytes from the horseshoe crab, *Limulus polyphemus*. A European Pharmacopœia Biological Reference Preparation of Endotoxin calibrated in International Units has been established for use in this test. It is expected that this *in vitro* test will find progressive application in appropriate monographs of both the British and European Pharmacopœias in place of the *in vivo* test for pyrogens. With respect to monographs for medicinal substances of the British Pharmacopœia, the Commission has embarked on a programme of seeking the necessary information to allow such replacement.

Uniformity of Content As foreshadowed in the Introduction to the British Pharmacopœia 1988, procedures for carrying out the test for Uniformity of content of active ingredient have been added to a number of monographs for capsules and tablets. With certain exceptions all capsules and tablets containing less than 2 mg or less than 2 per cent of the active ingredient must meet the requirements of the relevant general monograph in this respect regardless of whether or not a procedure is specified in the particular individual monograph. It is the policy of the British Pharmacopœia Commission to continue to add procedures for determining the uniformity of content of active ingredient to specific monographs in Addenda.

Dissolution Test In continuation of the Commission's policy to add requirements for dissolution to appropriate monographs for capsules and tablets on a selective basis as suitable procedures are developed and validated, tests for dissolution have been added to the monographs for Ergotamine Tablets, Methysergide Tablets, Prednisolone Tablets and Prednisone Tablets.

European Pharmacopœia This Addendum contains edited versions of European Pharmacopœia material that has been published in fascicule 11 of the second edition of the European Pharmacopœia. With certain exceptions, the effective date for monographs in that fascicule is 1 January 1989.

Use of Animals The Commission has continued to pursue its policy of reducing reliance on *in vivo* test methods wherever this is deemed compatible with its primary objective of providing satisfactory pharmacopœial standards. Liquid chromatographic assays have replaced biological assays for Gonadorelin and for the oxytocin component of Ergometrine and Oxytocin Injection.

Acknowledgements The British Pharmacopœia Commission records its continued indebtedness to the members of its advisory Committees and Consultative Groups. Without their dedicated enthusiasm and assistance its objectives could not be achieved.
Finally the Commission wishes to express its appreciation of the outstanding contribution made over twenty-five years by Dr C A Johnson, CBE, who was Senior Scientific Assistant from 1963, Scientific Director from 1966 and Secretary and Scientific Director from 1976 until his retirement in January 1988. Sadly, Dr Johnson died on 2 May 1988.

Additions The following monographs are added to the British Pharmacopœia 1988 by means of this Addendum.

Medicinal and Pharmaceutical Substances

Pizotifen Malate

Formulated Preparations

ORAL LIQUIDS

Acid Gentian Mixture

Nitrazepam Oral Suspension

PARENTERAL PREPARATIONS

Ascorbic Acid Injection

Menadiol Phosphate Injection

Procyclidine Injection

TABLETS

Pizotifen Tablets

Pseudoephedrine Tablets

Amendments

The following monographs of the British Pharmacopœia 1988 are amended by means of this Addendum.

Medicinal and Pharmaceutical Substances

Ampicillin Sodium
Aprotinin
Baclofen
Betamethasone Sodium Phosphate
Calcitonin (Pork)
Cephadrine
Chlordiazepoxide
Chloroxylenol
Clomiphene Citrate
Codeine Hydrochloride
Cycloserine
Danthron
Dequalinium Chloride
Dichlorphenamide
Disopyramide Phosphate
Ecothiopate Iodide
Fosfestrol Sodium
Glipizide
Glucagon
Gonadorelin
Ibuprofen
Ketoprofen
Lactulose Solution
Levamisole Hydrochloride
Lorazepam
Mefenamic Acid
Megestrol Acetate
Menadiol Sodium Phosphate
Mexenone
Minocycline Hydrochloride
Morphine Sulphate
Nandrolone Decanoate
Nandrolone Phenylpropionate
Nicotiny Alcohol Tartrate
Oxazepam
Pancuronium Bromide
Phenol
Prazosin Hydrochloride
Procyclidine Hydrochloride
Pseudoephedrine Hydrochloride
Sodium Diatrizoate
Sodium Metabisulphite
Sumatra Benzoin
Testosterone
Tobramycin
Vincristine Sulphate

Formulated Preparations

CAPSULES
Capsules
Cephadrine Capsules
Chlordiazepoxide Capsules
Diazepam Capsules
Indomethacin Capsules
Mefenamic Acid Capsules
Phenytoin Capsules
Rifampicin Capsules

CREAMS
Cetrimide Cream
Fluorouracil Cream
Gentamicin Cream
Hydrocortisone and Neomycin Cream
Urea Cream

EAR DROPS

Chloramphenicol Ear Drops

EXTRACTS

Deglycyrrhised Liquorice Extract

EYE DROPS

Cyclopentolate Eye Drops

EYE OINTMENTS

Chlortetracycline Eye Ointment

OINTMENTS

Gentamicin Ointment

Methyl Salicylate Ointment

ORAL LIQUIDS

Aqueous Iodine Oral Solution

Aromatic Magnesium Carbonate Mixture

Benorylate Oral Suspension

Calciferol Oral Solution

Ephedrine Elixir

Promethazine Oral Solution

Paediatric Trimeprazine Oral Solution

Rifampicin Oral Suspension

Strong Paediatric Trimeprazine Oral Solution

PARENTERAL PREPARATIONS

Ampicillin Injection

Aprotinin Injection

Betamethasone Injection

Choramphenicol Sodium Succinate Injection

Cortisone Injection

Ergometrine and Oxytocin Injection

Fluorouracil Injection

Fortified Procaine Penicillin Injection

Gentamicin Injection

Gonadorelin Injection

Melphalan Injection

Methotrexate Injection

Nandrolone Decanoate Injection

Nandrolone Phenylpropionate Injection

Pancuronium Injection

Phenytoin Injection

Phytomenadione Injection

Prednisolone Sodium Phosphate Injection

Procaine Penicillin Injection

Protamine Sulphate Injection

Spectinomycin Injection

Testosterone Implants

Thiamine Injection

Tubocurarine Injection

SOLUTIONS

Monosulfiram Solution

SPIRITS

Surgical Spirit

SUPPOSITORIES

Indomethacin Suppositories

TABLETS

Ascorbic Acid Tablets

Atenolol Tablets

Baclofen Tablets

Benzotropine Tablets

Betamethasone Sodium Phosphate Tablets

Busulphan Tablets

Chlordiazepoxide Tablets

Chlordiazepoxide Hydrochloride Tablets

Cortisone Tablets
 Diazepam Tablets
 Dichlorphenamide Tablets
 Dispersible Aspirin Tablets
 Effervescent Potassium Chloride Tablets
 Ergotamine Tablets
 Ferrous Succinate Tablets
 Ferrous Sulphate Tablets
 Fludrocortisone Tablets
 Folic Acid Tablets
 Griseofulvin Tablets
 Haloperidol Tablets
 Imipramine Tablets
 Lithium Carbonate Tablets
 Lorazepam Tablets
 Melfalan Tablets
 Mepyramine Tablets
 Methotrexate Tablets
 Methysergide Tablets

Metronidazole Tablets
 Nicotiny Alcohol Tablets
 Paracetamol Tablets
 Phenytoin Tablets
 Prazosin Tablets
 Prednisolone Tablets
 Prednisone Tablets
 Soluble Aspirin Tablets
 Thiamine Tablets
 Trimeprazine Tablets
 Warfarin Tablets

Immunological Products

Inactivated Influenza Vaccine (Surface Antigen)

Surgical Materials

Absorbent Cotton and Viscose Wadding
 Elastic Adhesive Bandage
 Elasticated Tubular Bandage

European Pharmacopœia

Monographs of the European Pharmacopœia that are reproduced in edited form in this Addendum replace the monographs in the British Pharmacopœia 1988. Where a monograph appears in the British Pharmacopœia under a different title, the British Pharmacopœia title is given in parentheses.

REVISED MONOGRAPHS

Medicinal and Pharmaceutical Substances

Ascorbic Acid
 Bacitracin Zinc
 Benzylpenicillin Potassium
 Benzylpenicillin Sodium
 Calcium Carbonate
 Calcium Chloride
 Chlordiazepoxide Hydrochloride
 Cholecalciferol
 Cholecalciferol Concentrate (Oily Form)
 Cholecalciferol Concentrate (Powder Form)
 Codeine Phosphate Hemihydrate (Codeine Phosphate)
 Disodium Phosphate Dodecahydrate (Sodium Phosphate)
 Ergocalciferol
 Ethinylestradiol (Ethinylloestradiol)
 Hydrocortisone
 Magnesium Chloride
 Methyldopa
 Nitrazepam

Papaverine Hydrochloride
 Potassium Chloride
 Purified Talc
 Purified Water
 Sodium Acetate
 Sodium Carboxymethylcellulose (Carmellose Sodium)
 Sodium Chloride
 Trimethoprim
 Valerian
 Water for Injections
 Zinc Oxide

Formulated Preparations

Haemodialysis Solutions

Immunological Products

Influenza Vaccine (Inactivated)
 (Inactivated Influenza Vaccine)

Radiopharmaceutical Preparations

Technetium^[99mTc] Macroalb Injection

NEW MONOGRAPHS

Medicinal and Pharmaceutical Substances

Bupivacaine Hydrochloride
 Busulfan (Busulphan)
 Carbamazepine
 Cetyl Alcohol
 Chloroquine Phosphate
 Chloroquine Sulphate
 Chlortalidone (Chlorthalidone)
 Dexamethasone Acetate*
 Dexamethasone Sodium Phosphate
 Diazoxide
 Dihydroergotamine Mesilate
 (Dihydroergotamine Mesylate)

Erythromycin Estolate
 Ethambutol Hydrochloride
 Lynestrenol (Lynoestrenol)
 Mannitol
 Methylprednisolone
 Penicillamine
 Procainamide Hydrochloride
 Propranolol Hydrochloride
 Protamine Sulphate
 Sodium Cromoglicate (Sodium Cromoglycate)
 Sodium Nitroprusside
 Timolol Maleate
 Verapamil Hydrochloride