British Pharmacopoeia 2000

Volume 3

British Pharmacopoeia (Veterinary) 2000

Published on the recommendation of the Medicines Commission pursuant to the Medicines Act 1968 and notified in draft to the European Commision in accordance with Directive 98/34/EEC

The monographs of the Third Edition of the European Pharmacopoeia (1997), as amended by the Supplement 2000 published by the Council of Europe in September 1999, are reproduced either in this edition of the British Pharmacopoeia (Veterinary) or in the associated edition of the British Pharmacopoeia
see General Notices, page 3

Effective date: 1 December 2000
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London: The Stationery Office

In respect of Great Britain:
THE DEPARTMENT OF HEALTH
THE MINISTRY OF AGRICULTURE, FISHERIES AND FOOD
In respect of Northern Ireland:
THE DEPARTMENT OF HEALTH, SOCIAL SERVICES AND PUBLIC SAFETY
THE DEPARTMENT OF AGRICULTURE AND RURAL DEVELOPMENT

Published by The Stationery Office under licence from the Controller of Her Majesty's Stationery Office for the Department of Health on behalf of the Agriculture Ministers

First Published 2000

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Dd.....
ISBN 0 11 322320 X

Printed in the United Kingdom by the Stationery Office Limited under the authority and superintendence of the Controller of Her Majesty's Stationery Office and Queen's Printer of Acts of Parliament

British Pharmacopoeia (Veterinary) 2000

Notices

Any reference to a monograph, an appendix or a reagent that is not contained within this edition of the British Pharmacopoeia (Veterinary) is to be construed as a reference to the said monograph, appendix or reagent contained within the British Pharmacopoeia.

The term 'British Pharmacopoeia', used without qualification, means the British Pharmacopoeia 2000 modified as necessary by amendments.

Where a preparation that is the subject of a monograph in the British Pharmacopoeia is supplied for use in veterinary practice, the standards of the British Pharmacopoeia apply, unless otherwise justified and authorised.

The designation 'British Pharmacopoeia (Veterinary)' [BP(Vet)] may be used in place of the designation 'British Pharmacopoeia' [BP] for a preparation complying with a monograph in the British Pharmacopoeia, where such a preparation is supplied for use in veterinary practice with the approval of the competent authority.

Monographs of the European Pharmacopoeia are distinguished by a chaplet of stars against the title. The term European Pharmacopoeia, used without qualification, means the third edition of the European Pharmacopoeia comprising, unless otherwise stated, the main volume, published in 1996 as amended by any subsequent supplements and revisions.

Patents

In this Pharmacopoeia 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 Pharmacopoeia neither conveys, nor implies, licence to manufacture.

Effective dates

Much of the material in this edition enters into force on 1 December 2000 but certain material that has been published earlier by Gazette Notices became effective on the date stated in the relevant entry.

Preface

The British Pharmacopoeia (Veterinary) 2000 is published for the Agriculture 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 appreciation for the services of all who have contributed to the preparation of this work. Together with the British Pharmacopoeia 2000, to which it is a companion volume, it should be of great value to all those concerned with the quality of materials used in the practice of veterinary medicine.

British Pharmacopoeia Commission

The British Pharmacopoeia Commission is appointed by the Secretary of State concerned with health in Great Britain, the Minister of Agriculture, Fisheries and Food, the Department of Health, Social Services and Public Safety for Northern Ireland and the Department of Agriculture and Rural Development for Northern Ireland, acting jointly, in exercise of their powers under section 4 of the Medicines Act 1968.

The duties of the British Pharmacopoeia Commission are as follows:

(a) the preparation under section 99(1) of the Act of any new edition of the British Pharmacopoeia;

(b) the preparation under section 99(1) of the Act, as given effect by section 102(1) thereof, of any amendments of the edition of the British Pharmacopoeia published in 1968 or any new edition of it;

(c) the preparation under section 100 of the Act (which provides for the preparation and publication of lists of names to be used as headings to monographs in the British Pharmacopoeia) of any list of names and the preparation under that section as given effect by section 102(3) of the Act of any amendments of any published list;

(d) the preparation under section 99(3)(b) of the Act of any compendium or any new edition thereof;

(e) the preparation under section 99(3)(b) of the Act, as given effect by section 102(1) thereof, of any amendments to any such compendium.

Members of the British Pharmacopoeia Commission are appointed by Ministers, having regard to recommendations made by the Medicines Commission. Appointments are usually for a (renewable) term of 4 years.

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[1]Term of office ends 31 December 2001
[2] Resigned March 1999

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Introduction

This edition of the British Pharmacopoeia (Veterinary) has been prepared by the British Pharmacopoeia Commission in accordance with the Medicines (British Pharmacopoeia Commission) Amendment Order 1982 (SI 1982 No. 1335). This empowers the British Pharmacopoeia Commission to prepare a compendium under section 99(3)(b) of the Medicines Act 1968 containing information relating to substances and articles which are or may be used in the practice of veterinary medicine or veterinary surgery. Under the terms of section 65 of the Medicines Act 1968 it is an offence to sell or supply a medicinal product in the United Kingdom that is the subject of a monograph in the Pharmacopoeia if that product does not comply with the standards specified in the monograph.

This edition is published as a companion volume to the British Pharmacopoeia 2000 and thus contains only those monographs for substances and preparations used exclusively or predominantly in veterinary medicine within the United Kingdom, together with such additional texts as are necessary to support them. It therefore follows that any reference to a monograph, appendix or reagent not contained within this volume is to be construed as a reference to the said monograph, appendix or reagent contained within the British Pharmacopoeia 2000.

This new edition together with the British Pharmacopoeia 2000 contains all the monographs of the 3rd edition of the European Pharmacopoeia as amended by the Supplement 2000. Users of the British Pharmacopoeia and British Pharmacopoeia (Veterinary) therefore benefit by finding within these two comprehensively indexed editions all current pharmacopoeial standards for veterinary medicines used within the United Kingdom.

Effective date

The effective date for this edition, which supersedes the British Pharmacopoeia (Veterinary) 1999 as amended by Amendments sheet No. 1, is 1st December 2000 unless otherwise stated for an entry by an italicised statement showing the month and year of its implementation. Such italicised statements are given for certain monographs reproduced from the European Pharmacopoeia and are located below the chaplet of stars that appears alongside the monograph title, for example *'1/00'*.

Where a monograph which appeared previously in an earlier edition of the British Pharmacopoeia (Veterinary) has not been included in this new edition it remains effective in accordance with section 65(4) of the Medicines Act 1968.

Additions and Revisions

A list of monographs included within this pharmacopoeia for the first time is given at the end of this introduction. It includes 3 new monographs reproduced from the 1999 supplement of the European Pharmacopoeia.

Monographs which have been amended technically by means of this edition are also listed at the end of this introduction. For the benefit of the reader this list indicates the section, or sections, of each monograph which has/have been revised.

European Pharmacopoeia

All monographs of the 3rd edition of the European Pharmacopoeia as amended by Supplement 2000 which are used in veterinary practice but not normally in human medicine in the United Kingdom, are reproduced in this edition. Each of these monographs is signified by an European chaplet of stars alongside its title. Additionally, explicit reference is made to the European Pharmacopoeia within an italicised introductory statement. The entire European Pharmacopoeia text is then bounded by two horizontal lines bearing the symbol '*Ph Eur*'.

The European texts have been reproduced in their entirety without editorial modification but, where deemed appropriate, additional statements of relevance to UK usage have been added (*eg* a list of BP (Vet) preparations). It should be noted, however, that in the event of doubt of interpretation in any text of the European Pharmacopoeia, the text published in English under the direction of the Council of Europe should be consulted.

Correspondence between the general methods of the European Pharmacopoeia and the appendices of the British Pharmacopoeia (Veterinary) 2000 is indicated in each appendix. A check list is also provided at the beginning of the appendices section. This provides a full listing of the European Pharmacopoeia method texts with their British Pharmacopoeia and British Pharmacopoeia (Veterinary) equivalents.

Pharmacopoeial Requirements

Pharmacopoeial requirements for articles used in veterinary medicine are established on the same basis as those used in human medicine. A proper understanding of the basis upon which these requirements are established is essential for their application and advice is provided within the General Notices of the British Pharmacopoeia (Veterinary) and the Supplementary Chapters to the British Pharmacopoeia. It should be noted that no requirement of the Pharmacopoeia can be taken in isolation. A valid interpretation of any particular requirement depends upon it being read in the context of (i) the monograph as a whole, (ii) the specified method of analysis, (iii) the relevant General Notices and (iv) where appropriate, the relevant general monograph.

Where a preparation which is the subject of a monograph in the British Pharmacopoeia is supplied for use in veterinary medicine the standards of the British Pharmacopoeia apply unless otherwise justified and authorised. Attention is drawn to the Notice permitting the designation British Pharmacopoeia (Veterinary) [BP (Vet)] to be used in place of the designation British Pharmacopoeia [BP] where a preparation complying with the British Pharmacopoeia is supplied for use in veterinary medicine with the approval of the competent authority.

General Monographs The General Monographs, which are applicable only to veterinary dosage forms, are grouped together within this volume at the beginning of the Formulated Preparations section. They are followed by the individual dosage form monographs arranged in alphabetical order. The General Monographs of the European Pharmacopoeia apply to all individual dosage forms of the type defined rather than to only those preparations for which a specific monograph is described (see the General Notices).

Acknowledgements The British Pharmacopoeia Commission is greatly indebted to the members of its advisory Committees and Consultative Groups without whose dedicated enthusiasm and assistance this edition could not have been prepared. Close co-operation has continued with many organisations at home and overseas. These include the Veterinary Medicines Directorate, the Medicines Control Agency (of which the Pharmacopoeia secretariat and laboratory staff are a part), the National Institute for Biological Standards and Control, the Royal Pharmaceutical Society of Great Britain, the National Office of Animal Health, the Association of the British Pharmaceutical Industry, the European Pharmacopoeia Commission, the Therapeutic Goods Administration (Australia), the Health Protection Branch of the Canadian Department of Health and Welfare, the Committee of Revision of the United States Pharmacopeia, the Essential Drugs and Other Medicines Department of the World Health Organization (WHO) and the WHO Collaborating Centre for Chemical Reference Substances.

Additions

The following monographs of the British Pharmacopoeia (Veterinary) 2000 were not included in the British Pharmacopoeia (Veterinary) 1999.

Medicinal and Pharmaceutical Substances
Detomidine Hydrochloride*
Xylazine Hydrochloride*

Immunological Products
Avian Paramyxovirus 3 Vaccine, Inactivated*

Omissions

The following monographs of the British Pharmacopoeia (Veterinary) 1999 are not included in the British Pharmacopoeia (Veterinary) 2000.

Formulated Preparations
Amprolium and Ethopabate Premix
Furazolidone Oral Suspension
Furazolidone Premix
Tiabendazole Oral Suspension
Triamcinolone Acetonide Injection

Immunological Products
African Horsesickness Vaccine, Living
Bluetongue Vaccine, Living
Brucella Abortus (Strain 19) Vaccine, Living
Brucella Abortus (Strain 45/20) Vaccine, Inactivated
Canine Contagious Hepatitis Vaccine, Inactivated
Contagious Bovine Pleuropneumonia Vaccine, Living
Rinderpest Vaccine, Living
Salmonella Choleraesuis Vaccine, Living
Johnin Purified Protein Derivative

Technical Changes The following monographs in the BP(Vet) 2000 have been technically amended since the publication of the BP(Vet) 1999. This list does not include revised monographs of the European Pharmacopoeia. An indication of the nature of the change or the section of the monograph that has been changed is given in *italic type* in the right hand column.

Medicinal and Pharmaceutical Substances	
Fluanisone	*(Characteristics, Identification)*
Oxfendazole	*(Replaced by Ph Eur monograph)*
Silica in Dimeticone Suspension	*(Replaced by BP monograph for Simeticone for Oral Use)*
Formulated Preparations: Specific Monographs	
Levamisole Injection	*(Acidity)*
Procaine Benzylpenicillin Intramammary Infusions	*(Identification)*
Immunological products	
Contagious Pustular Dermatitis Vaccine, Living	*(Revision of most sections)*
Louping-ill Vaccine	*(Revision of most sections)*
Lungworm (Dictyocaulus Viviparus) Oral Vaccine, Living	*(Revision of most sections)*
Ovine Enzootic Abortion Vaccine, Inactivated	*(Revision of most sections)*

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General Notices

Contents of the General Notices