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British Pharmacopoeia (Veterinary) 1998

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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 1998 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.

Preface

The British Pharmacopoeia (Veterinary)1998 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 1998, 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 England, the Secretaries of State respectively concerned with health and with agriculture in Wales and 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 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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Secretary and Scientific Director

[1]Term of office ended 31 December 1995.
[2]Term of office ends 31 December 1997.
[3]Term of office ends 31 December 1999.
[4]Deceased December 1994
[5]Vice-Chairman from March 1995
[6] resigned December 1997

R C Hutton BSc PhD CChem FRSC

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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 new edition of the British Pharmacopoeia (Veterinary) supersedes that published in 1993 as amended by its 1995 and 1996 Addenda and subsequent Amendments Sheets. In accordance with the policy that the standards for articles used in veterinary medicine should generally be identical to those for the same articles used in human medicine and in pursuance of the objective of harmonising and integrating the British Pharmacopoeia and the British Pharmacopoeia (Veterinary) as far as possible, this edition is published as a companion volume to the British Pharmacopoeia 1998. The effective date of both Pharmacopoeias is 1 December 1998. As a companion volume to the British Pharmacopoeia 1998, the British Pharmacopoeia (Veterinary) 1998 contains only those monographs for substances and preparations that are used exclusively or predominantly in veterinary medicine in the United Kingdom together with any additional appendices that are necessary to support these texts. This avoids duplication and the consequent difficulties of maintaining harmony between the separate compendia. It follows that, as stated in the 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.

Revision In addition to improvements to the requirements of individual monographs such as the revision of the monograph for Cloprostenol Injection, technical revision of specifications in this new edition includes a review and rationalisation of identification tests to reduce the burden of testing, wherever possible. The policy of the British Pharmacopoeia Commission with respect to monographs developed in recent years has been to include the minimum number of tests for identification commensurate with providing adequate asurance of identity of the substance or preparation being examined (see General Notices). In many monographs reliance is now placed on infrared spectroscopy together, where relevant, with a test for the counter ion. This policy has

now been extended by reviewing earlier monographs especially those for which four or more identification tests were specified and removing any tests considered superfluous.

To assist users of the Pharmacopoeia a list has been included at the end of the Introduction indicating those monographs which have been technically amended by means of this edition.

In preparing this edition the practice of cross-referencing from a monograph for a formulated preparation to the corresponding monograph for the parent substance has been significantly reduced. In particular cross references to monographs from the European Pharmacopoeia have been removed. The relevant tests are now included in full in the monograph for the formulated preparation. Where there are several monographs for formulated preparations, a cross reference from one preparation to another may be given, where appropriate.

European Pharmacopoeia

Monographs of the third edition of the European Pharmacopoeia for substances or preparations that are used in veterinary practice but that are not normally used in human medicine are reproduced in this edition of the British Pharmacopoeia (Veterinary). Many of these monographs are to be found in the section on Immunological products.

Changes have been made in this edition to the way in which the monographs of the European Pharmacopoeia are presented in order to distinguish them more clearly from monographs that are specific to the British Pharmacopoeia (Veterinary). In addition to the European 'chaplet of stars' symbol alongside the title, European Pharmacopoeia monographs are distinguished by an explicit reference to the European Pharmacopoeia within an italicised introductory statement. The beginning and end of the full text of the European Pharmacopoeia monograph is indicated clearly by means of horizontal lines bearing the symbol '*Ph Eur*' ranged left and right; the text is included without any editorial modification.

Where appropriate, the monographs provide additional statements of relevance to UK usage (such as the list of BP (Vet) preparations). All such statements are placed together at the head of the monograph for ease of reference.

Correspondence between the general methods of the European Pharmacopoeia and the appendices of the BP(Vet)1998 is indicated in each appendix. A check list at the beginning of the Appendices gives a full listing of the European Pharmacopoeia method texts with their British Pharmacopoeia or British Pharmacopoeia (Veterinary) equivalents. Attention is drawn to this check list by means of a note at the foot of all pages in the relevant sections of the Pharmacopoeia devoted to monographs.

The General Notices of the European Pharmacopoeia have been reproduced in full at the end of the relevant section of this edition. They are provided for application to the monographs and other texts from the European Pharmacopoeia.

While the above changes are designed to assist users of the British Pharmacopoeia (Veterinary), it is emphasised that in the event of doubt of interpretation of such texts the European Pharmacopoeia text published in English under the direction of the Council of Europe must be consulted. A General Notice stresses the mandatory nature of this injunction.

General Notices The British Pharmacopoeia (Veterinary) comprises the entire text within the publication. The interpretation of the Pharmacopoeia is governed by the General Notices. In this edition, the General Notices are presented in three parts each of which is introduced by an italicised statement. The first part includes a notice concerning incorporation of monographs from the European Pharmacopoeia. The second part applies to all text other than that reproduced from the European Pharmacopoeia. The third part consists of the entire General Notices of the European Pharmacopoeia that apply to all texts from the European Pharmacopoeia. While this approach results in a certain amount of repetition within the General Notices as a whole, providing separate notices for the interpretation of text specific to the British Pharmacopoeia (Veterinary) and of text from the European Pharmacopoeia is intended to be more convenient to the user of the Pharmacopoeia. Such a separation is consistent with the clearer distinction that is being made between these texts of different provenance.

A statement has been added within the second part of the General Notices to the notice on Assays and Tests to indicate that a temperature in a test for Loss on drying, where no range is given, implies a range of ±2° around the stated temperature.

Changes in title A list of the monographs of the British Pharmacopoeia (Veterinary) 1993 for which the title has been changed in the British Pharmacopoeia (Veterinary) 1998 is provided at the end of this Introduction. These changes are necessary to bring the titles in the British Pharmacopoeia (Veterinary) in line with the names that manufacturers are now required to use on product labels and leaflets in accordance with EC Directive 81/851/EEC.

Normal practice within the British Pharmacopoeia (Veterinary) when changing the title of a monograph is to retain the former title as a subsidiary title for at least one edition. This is not possible for these changes since use of the former name is not permitted on product labels etc. In order to provide continuity a statement has therefore been added to all affected monographs and a cross-referenced entry has been included in the Index. These statements are in the form 'When [BP(Vet) 93 title] is prescribed or demanded, [BP(Vet) 98 title] shall be dispensed or supplied.' For example the monograph for Pentobarbital Injection includes the following statement 'When pentobarbitone injection is prescribed or demanded, Pentobarbital Injection shall be dispensed or supplied.' Statements of this type are an established feature of certain monographs where it is considered advisable to provide a link between the name at the head of a monograph and some other 'unofficial' descriptor that may still be used by prescribers or purchasers of veterinary medicines for the same substance or preparation. Inclusion of such an 'equivalence statement' within the British Pharmacopoeia (Veterinary) provides an official, primary source of authoritative information.

The title changes discussed above are also been reflected in consequential changes throughout the texts of the affected monographs, other than in monographs of European Pharmacopoeia origin; they are also reflected in the list of Approved Synonyms (see below).

Approved Synonyms

A consolidated list of Approved Synonyms for Veterinary Substances and Preparations is published as Appendix XXI B. In consolidating the lists from the Addenda to the British Pharmacopoeia (Veterinary) 1993 changes have been made on the following basis.

The Ph Eur title is the English main title given in the European Pharmacopoeia. Omission of the Latin sub-titles and consequent re-arrangement in alphabetical order of English title provides a simpler, more easily used list. To assist the user further, vaccines, antisera and diagnostics have been grouped together in a separate section for Immunological Products.

Changes have also been made to the consolidated list to reflect the changes in monograph titles described above. Those Approved Synonyms that were previously required in order to allow use of a BAN in a British Pharmacopoeia (Veterinary) monograph title in place of the rINN used in the corresponding European Pharmacopoeia title have been omitted.

A complete list of all Approved Synonyms is published as Appendix XXI B of the British Pharmacopoeia.

The Basis of Pharmacopoeial Requirements

A proper understanding of the basis on which the requirements of the Pharmacopoeia are established is essential to the correct interpretation of the requirements. Pharmacopoeial requirements for articles used in veterinary medicine are established on the same basis as those for articles used in human medicine. Some key features of pharmacopoeial requirements relevant to this edition of the British Pharmacopoeia (Veterinary) are described below. A more extensive commentary is provided in Supplementary Chapter I of the British Pharmacopoeia 1998.

The Pharmacopoeia contributes significantly to the overall control of the quality of medicinal products and provides a publicly available statement concerning the quality that a product or a component of a product is expected to meet at any time during its period of use. A manufacturer must recognise that a product or material may be challenged at any time during its claimed period of use by the methods of the Pharmacopoeia and that it must then comply with the pharmacopoeial requirements. Frequently a manufacturer will need to apply more stringent test limits at the time of release of a batch of the product or material in order to ensure compliance. The requirements included in a monograph, other than any instructions given under the side-heading Production are designed to provide the means by which an independent judgement can be made as to the overall quality of a particular article. A manufacturer in possession of detailed knowledge of the manufacturing process may have no need to carry out certain tests routinely. As stated in the General Notices, a manufacturer may assure himself by other means that the requirements of the Pharmacopoeia will be met. It is emphasised that the circumstances under which, and the frequency with which, tests of the Pharmacopoeia should be performed by a manufacturer as part of his overall quality assurance are ultimately matters for agreement between the manufacturer and the competent authority. In the event of any doubt or dispute as to whether or not a material is of pharmacopoeial quality, as the General Notice on Assays and Tests makes clear, the methods of the Pharmacopoeia are alone authoritative.

In addition to any advice or information provided in the Supplementary Chapters of the British Pharmacopoeia or in this Introduction , it is important to note that the status, scope and interpretation of Pharmacopoeial statements is governed by the General Notices. No requirement of the Pharmacopoeia can be taken in isolation; a valid interpretation of any particular requirement depends on it being read in the context of (i) the specified method of analysis (which may include reference to an Appendix), (ii) the monograph as a whole, (iii) where appropriate, the relevant general monograph and (iv) the relevant General Notices.

International Units

The term 'Unit' has been replaced, wherever appropriate in this edition, by 'IU' the abbreviation for International Unit. In previous editions of the Pharmacopoeia, the General Notice on Biological Assays and Tests stated that, wherever possible, the primary standard was the respective International Standard or Reference Preparation and that the Unit was the International Unit. Using 'IU' within all relevant texts is, however, more transparent than relying on this General Notice alone.

Monographs will continue to refer to units other than International Units, where appropriate, for example, for certain enzymes for which the primary standard is a reference preparation established by the International Pharmaceutical Federation (FIP) and adopted by the European Pharmacopoeia Commission (see also Supplementary Chapter I H). Labelling statements in monographs, other than those from the European Pharmacopoeia, which require the use of IU will retain the term 'Unit' in parentheses after 'IU' for an interim period to avoid confusion and to allow those manufacturers that currently label their products in Units to continue to use existing labels.

Formulated Preparations

In conformity with the British Pharmacopoeia 1998, the general monographs are grouped at the beginning of the section, followed by the individual monographs arranged in alphabetical order. The monographs included here are for preparations that are used exclusively or predominantly in veterinary practice. Where a preparation that 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. Particular 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.

In addition to general monographs for those types of dosage forms such as intramammary infusions that are used exclusively in veterinary medicine, the sub-section for General Monographs includes a list of those relevant general monographs of the British Pharmacopoeia that include requirements reproduced from the European Pharmacopoeia. These general provisions of the European Pharmacopoeia apply, unless otherwise justified and authorised, to all veterinary dosage forms of the type defined, whether or not an individual monograph is included in the British Pharmacopoeia (Veterinary). Where modified or additional requirements that apply only to the individual formulation monographs of the British Pharmacopoeia (Veterinary) are provided, the additional text is identified by a sub-heading such as 'Tablets of the British

Pharmacopoeia (Veterinary)' and by an italicised statement clarifying its sphere of application.

Appendices New Appendices have been created to accommodate certain general texts and methods of the European Pharmacopoeia. For example, Appendix XV(Vet) contains a collection of general texts on the production and testing of veterinary vaccines that were previously appended to the general monograph for veterinary vaccines.

A list of the contents of the Appendices of the British Pharmacopoeia (Veterinary) 1998 is provided at the beginning of the Appendices together with a list of European Pharmacopoeia general methods each with its British Pharmacopoeia or British Pharmacopoeia (Veterinary) Appendix equivalent.

Index A fully comprehensive index is provided in this edition. Page numbers given in **bold type** differentiate references to monographs from references to other parts of the Pharmacopoeia. Page numbers in normal type include: references to the Introduction, distinguished by the use of roman numerals; references to the infrared spectra, distinguished by page numbers preceded by the letter S and references to the Appendices distinguished by page numbers preceded by the letter A. For the convenience of the user, an explanatory key to page references is provided in a note at the foot of all pages of the index.

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 Medicines Control Agency (of which the Pharmacopoeia secretariat and laboratory staff are a part), the Veterinary Medicines Directorate, the National Institute for Biological Standards and Control, the Department of Pharmaceutical Sciences of the Pharmaceutical Society of Great Britain, the National Office of Animal Health, the Association of the British Pharmaceutical Industry, the Laboratory of the Government Chemist, 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 Pharmaceuticals and Biological Units of the World Health Organization (WHO) and the WHO Collaborating Centre for Chemical Reference Substances.

Finally, special thanks are due to the staff of The Stationery Office who have given enthusiastic help to the staff of the British Pharmacopoeia Commission in the production of this edition.

Additions The following monographs of the British Pharmacopoeia (Veterinary) 1998 were not included in the British Pharmacopoeia (Veterinary)1993 as amended by the Addendum 1995, the Addendum 1996 and Amendments No 3.

Medicinal and Pharmaceutical Substances
Fenbendazole*
Flunixin Meglumine

Immunological Products
Bovine Parainfluenza Virus Vaccine, Living*
Bovine Respiratory Syncytial Virus Vaccine, Living*
Feline Viral Rhinotracheitis Vaccine, Inactivated*

Surgical Materials
Sutures for Veterinary Use
Sterile Catgut in Distributor for Veterinary Use*
Sterile Linen Thread in Distributor for Veterinary Use*
Sterile Poly(Ethylene Terephthalate) Suture in Distributor for Veterinary Use*
Sterile Polyamide 6 Suture in Distributor for Veterinary Use*
Sterile Polyamide 6/6 Suture in Distributor for Veterinary Use*
Sterile Braided Silk Suture in Distributor for Veterinary Use*
Sterile Non-absorbable Strands in Distributor for Veterinary Use*

*Monograph of the European Pharmacopoeia

Omission The following monograph of the British Pharmacopoeia (Veterinary) 1993 as amended by the Addendum 1995, the Addendum 1996 and Amendments No 3 is not included in the British Pharmacopoeia 1998.

Pharmaceutical and Medicinal Substances
Powdered Catechu

Technical Changes The following monographs included in the British Pharmacopoeia (Veterinary)1998 have been amended technically since the publication of the British Pharmacopoeia (Veterinary)1993 as amended by the Addendum1995, the Addendum1996 and Amendments No 3. Ths list does not include monographs of the European Pharmacopoeia. The titles given in this list are those used in the British Pharmacopoeia (Veterinary)1998; changes in title from the British Pharmacopoeia (Veterinary) 1993 are given in the separate list below.

Medicinal and Pharmaceutical Substances
Cloprostenol Sodium
Silica in Dimeticone Suspension

Formulated Preparations
Cloprostenol Injection
Iron Dextran Injection

Immunological Products
Egg-drop Syndrome 76 Adenovirus Vaccine†
Feline Infectious Enteritis Vaccine, Living†
Feline Viral Rhinotracheitis Vaccine, Living†

†Monograph replaced by a monograph of the European Pharmacopoeia