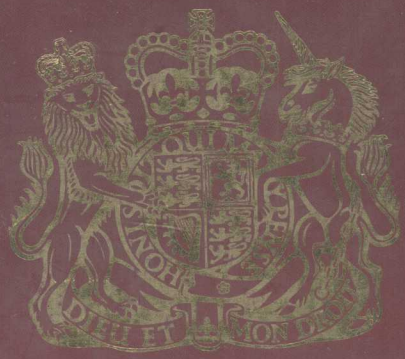

British Pharmacopoeia 2010

Volume I

Introduction

General Notices

Monographs

Medicinal and Pharmaceutical Substances (A- I)

Incorporating the requirements of the 6th edition of the European Pharmacopoeia as amended by Supplements 6.1 to 6.5

British Pharmacopoeia 2010

Volume I

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

The monographs of the Sixth Edition of the European Pharmacopoeia (2007), as amended by Supplements 6.1 to 6.5 published by the Council of Europe, are reproduced either in this edition of the British Pharmacopoeia or in the associated edition of the British Pharmacopoeia (Veterinary).

See General Notices

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FOREWORD

Since 1864, the British Pharmacopoeia has been providing authoritative official standards for pharmaceutical substances and medicinal products. The 2010 edition (BP 2010) continues this tradition. It makes an important contribution, therefore, to the role of the Medicines and Healthcare products Regulatory Agency in protecting public health by setting publicly available standards for the quality of medicines.

In addition to expanding the numbers of monographs for licensed formulated products, this edition continues to support regulatory work in the fields of herbal and complementary medicines by providing new monographs and guidance on the elaboration of BP monographs for traditional herbal medicines. The 2010 edition continues to improve the control of the quality of unlicensed medicines by providing standards for extensively used unlicensed formulations together with guidance on preservative-free unlicensed medicines and bioequivalence of oral suspensions.

The launch of a new website, www.pharmacopoeia.gov.uk, has improved the regulatory transparency of the British Pharmacopoeia in line with the principles contained in the Hampton Review and the central government's initiative on Better Regulation. It also increases the scope of information available to stakeholders and allows the BP Secretariat to move towards increased electronic working.

The British Pharmacopoeia maintains close ties with the work of the European Pharmacopoeia and continues to play a significant role in the standard-setting process in Europe, participating in the activities of the European Directorate for the Quality of Medicines and HealthCare, and influencing the decisions of the European Pharmacopoeia Commission through the United Kingdom Delegation. The texts and monographs of the European Pharmacopoeia form an integral part of the BP 2010.

Published annually, with the introduction of in-year electronic updates for this new edition, the British Pharmacopoeia is the only comprehensive collection of standards for UK medicinal substances. It is essential for all individuals and organisations involved in pharmaceutical research, development, manufacture, quality control and analysis.

Sir Alasdair Breckenridge
Chairman, MHRA

Contents

Contents of Volume IV

Notices

Monographs of the European Pharmacopoeia are distinguished by a chaplet of stars against the title. The term European Pharmacopoeia, used without qualification, means the sixth edition of the European Pharmacopoeia comprising, unless otherwise stated, the main volume, published in 2007 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 New and revised monographs of national origin enter into force on 1 January 2010. Monographs of the European Pharmacopoeia have previously been published by the Council of Europe and have been brought into effect by means of Notices published in the Belfast, Edinburgh and London Gazettes.

Preface

The British Pharmacopoeia 2010 is published for the Health Ministers on the recommendation of the Commission on Human Medicines in accordance with section 99(6) of the Medicines Act 1968.

The Commission on Human Medicines believes that the British Pharmacopoeia contributes significantly to the overall control of the quality of medicinal products by providing an authoritative statement of the quality that a product, material or article is expected to meet at any time during its period of use. The Pharmacopoeial standards, which are publicly available and legally enforceable, are designed to complement and assist the licensing and inspection processes and are part of the system for safeguarding purchasers and users of medicinal products.

The Commission on Human Medicines wishes to record its appreciation of the services of all those who have contributed to this important work.

British Pharmacopoeia Commission

The British Pharmacopoeia Commission is appointed, on behalf of the Secretary of State for Health, by the Appointments Commission, the body responsible for appointments to all of the Medicines Act 1968 Advisory Bodies.

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(6) of the Act, of any compendium, or any new edition thereof, containing information relating to substances and articles which are or may be used in the practice of veterinary medicine or veterinary surgery;

(e) to frame clear and unequivocal technical advice in order to discharge the Commission's responsibilities both for the British Pharmacopoeia, the British Pharmacopoeia (Veterinary) and British Approved Names and as the national pharmacopoeial authority with respect to the European Pharmacopoeia.

Members of the British Pharmacopoeia Commission are appointed for a (renewable) term of 4 years and, under the requirements laid down by the Office of the Commissioner for Public Appointments, can serve for a maximum of 10 years.

Expert Advisory Groups, Panels of Experts and Working Parties

Members of Expert Advisory Groups, Panels of Experts and Working Parties are appointed by the British Pharmacopoeia Commission.

The duties of the members are as follows:

(a) To collaborate in the preparation and revision of Monographs, Appendices and Supplementary Chapters for inclusion in the British Pharmacopoeia and British Pharmacopoeia (Veterinary).

(b) To collaborate in the preparation and revision of Monographs, Methods and General Chapters of the European Pharmacopoeia.

(c) To collaborate in the preparation and revision of the list of names to be used as titles for monographs of the British Pharmacopoeia and British Pharmacopoeia (Veterinary).

Members of Expert Advisory Groups, Panels of Experts and Working Parties are usually appointed for a (renewable) term of 4 years.

Membership of the British Pharmacopoeia Commission

The list below includes those members who served during the period 2008 to 2009.

Chairman Professor David Woolfson BSc PhD CChem FRSC FPSNI
Professor of Pharmaceutics, Queens University of Belfast

Vice-Chairman Mr V'Iain Fenton-May BPharm MI PharmM FRPharmS
Former Specialist Quality Controller to the Welsh Hospitals

Professor Graham Buckton BPharm PhD DSc AKC FRPharmS CChem FRSC
Professor of Pharmaceutics; School of Pharmacy, University of London

Professor Donald Cairns BSc PhD MRPharmS CSci CChem FRSC
Associate Head, School of Pharmacy and Life Sciences, Robert Gordon University, Aberdeen

Mr Barry Capon CBE MA DL (*Lay representative*)
Non-executive Director, Norfolk and Waveney Mental Health NHS Foundation Trust

Professor Alastair Davidson BSc PhD FRPharmS
Visiting Professor of Pharmaceutical Sciences, University of Strathclyde

Mrs Margaret A Dow MSc PhC
Consultant in the registration of biological and biotechnological products

Dr Thomas D Duffy BSc PhD FRPharmS CChem MRSC FCQI CQP MRQA
Director, Lowden International (providing consultancy and training to pharmaceutical organisations)

Mr Christopher Goddard BSc DIS CSci EurChem CChem FRSC
Quality Control Manager, Recipharm Limited

Dr Keith Helliwell BPharm PhD MRPharmS
Senior Technical Adviser, William Ransom & Son PLC

Dr Rodney L Horder BPharm PhD MRPharmS
Divisional Vice President, European Quality and Regulatory Strategy, Abbott

Dr Aileen M T Lee BVMS PhD MRCVS
Member of the Veterinary Medicines Directorate
Specialism: Regulation of Veterinary Immunological Products

Dr Lincoln Tsang BPharm LLB PhD FRSC FIBiol FRSA FRPharmS Solicitor
Life Sciences Lawyer; Partner, Arnold & Porter LLP

Mrs Josephine Turnbull LLB (*Lay representative*)
Chairman of Tees, Esk and Wear Valley NHS Trust

Professor Elizabeth Williamson BPharm PhD MRPharmS
Professor of Pharmacy, University of Reading

Professor Peter York BSc PhD DSc FRPharmS CChem FRSC
Professor of Physical Pharmaceutics, University of Bradford

Secretary and Scientific Director Dr Gerard Lee BPharm PhD FRPharmS MRSC CChem

Membership of Expert Advisory Groups, Panels of Experts and Working Parties

The Commission appointed the following Expert Advisory Groups, Panels of Experts and Working Parties to advise it in carrying out its duties. Membership has changed from time to time; the lists below include all who have served during the period 2008 to 2009.

EXPERT ADVISORY GROUPS

ABS: Antibiotics

R L Horder (*Chairman*), P York (*Vice-Chairman*), A Ambrose, A H Andrews, J F Chissell, P Ellis, S Green, R Harryman, A Livingstone, W Mann, S Patel, B White, I R Williams

HCM: Herbal and Complementary Medicines

E Williamson (*Chairman*), L A Anderson (*Vice-Chairman*), M Berry, P Bremner, K Chan, T Chapman, A Charvill, K Helliwell, C Leon, A C Moffat, J D Phillipson, M Pires, J Sumal

(*Corresponding member* B P Jackson)

MC1: Medicinal Chemicals

A G Davidson (*Chairman*), D Cairns (*Vice-Chairman*), M Ahmed, L Anderson, J C Berridge, M Broughton, A J Caws, P Fleming, W J Lough, D Malpas

MC2: Medicinal Chemicals

T D Duffy (*Chairman*), C T Goddard (*Vice-Chairman*), M Cole, B M Everett, S Jones, M A Lee, J Lim, K McKiernan, P Murray, M Turgoose

MC3: Medicinal Chemicals

V Fenton-May (*Chairman*), E Williamson (*Vice-Chairman*), S Arkle, J F Chissell, C T Goddard, W K L Pugh, W H Smith, R Tomlinson, R Torano, M Tubby, I R Williams

NOM: Nomenclature

J K Aronson (*Chairman*), L Tsang (*Vice-Chairman*), M Ahmed, G Gallagher, P W Golightly, A D McNaught, G P Moss, C Preston, R Thorpe, B Warner

(*Corresponding members* R G Balocco Mattavelli, E M Cortés Montejano, J Robertson)

PCY: Pharmacy

R L Horder (*Chairman*), A D Woolfson (*Vice-Chairman*), M Aulton, E Baker, S Branch, G Buckton, G Davison, G Eccleston, D Elder, R Lowe, B R Matthews, J F McGuire, S C Nichols

ULM: Unlicensed Medicines

V Fenton-May (*Chairman*), T D Duffy (*Vice-Chairman*), I Beaumont, A Charvill, P Forsey, W Goddard, S Jones, M A Oldcorne, A Pandya, N J Precious, J Rothwell, J Smith

PANELS OF EXPERTS

BIO: Biological and Biotechnological Products	M A Dow (*Chairman*), L Tsang (*Vice-Chairman*), A F Bristow, D H Calam, J Cook, J Lawrence, B Mason, A Onadipe, A M Pickett, S Poole, D Sesardic, P Sheppard, W J Tarbit, J N A Tettey, A H Thomas, R Thorpe
BLP: Blood Products	B Cuthbertson, A R Hubbard, S Jenkins, J Lawrence, P Varley
IGC: Inorganic and General Chemicals	C T Goddard (*Chairman*), A C Cartwright, B M Everett, P Henrys, D Malpas, C Mroz, I D Newton
MIC: Microbiology	V Fenton-May (*Chairman*), S Denyer, D P Hargreaves, B R Matthews, P Newby
RAD: Radioactive Materials	S R Hesslewood, A M Millar, R D Pickett, S Waters
VIP: Veterinary Immunological Products	A M T Lee (*Chairman*), A H Andrews, A M Brady, K Redhead, J Salt, P W Wells

WORKING PARTIES

CX: Excipients	G Buckton (*Chairman*), C Mroz (*Vice-Chairman*), E Anno, R Cawthorne, B R Matthews, M I Robertson

Current British Pharmacopoeia Staff

Secretariat M Vallender (*Editor-in-Chief*)

S Young (*Head of Science*)

M Barrett, L Caller, A Evans, J Francomb, P Holland, R A Pask-Hughes, J Pound, F J Swanson, R L Turner, M Whaley

Administrative M Cumberbatch, B F Delahunty, W Jeffries, D Myburgh, J Paine

ISO 9001
FS 27268

Current British Pharmacopoeia Laboratory Staff

J Gan, P Hansal, K Harper, M Kram, R Mannan, A Panchal, H Patel, K Patel, M Patel, N Patel, C Provis-Evans, P Webb

ISO 9001
FS 27613

Introduction

The British Pharmacopoeia 2010 supersedes the British Pharmacopoeia 2009. It has been prepared by the British Pharmacopoeia Commission, with the collaboration and support of its Expert Advisory Groups and Panels of Experts, and contains approximately 3300 monographs for substances, preparations and articles used in the practice of medicine. Some of these monographs are of national origin while others have been reproduced from the 6th edition of the European Pharmacopoeia. This edition, together with its companion edition, the British Pharmacopoeia (Veterinary) 2010, incorporates all the monographs of the 6th edition of the European Pharmacopoeia as amended by Supplements 6.1 to 6.5. The user of the British Pharmacopoeia thereby benefits by finding within this one, comprehensively indexed, compendium all current United Kingdom pharmacopoeial standards for medicines for human use. The new edition comprises five volumes as follows.

Volumes I and II	Medicinal Substances
Volume III	Formulated Preparations, Blood-related Products, Immunological Products, Radiopharmaceutical Preparations, Surgical Materials, Herbal Drugs, Herbal Drug Preparations and Herbal Medicinal Products and Materials for use in the Manufacture of Homoeopathic Preparations
Volume IV	Infrared Reference Spectra, Appendices, Supplementary Chapters and Index
Volume V	British Pharmacopoeia (Veterinary) 2010

Book Format

The formats of the British Pharmacopoeia are regularly reviewed. For this new edition, the weight of the book format has been reduced with the use of a lighter weight paper.

Effective Date

The effective date for this edition is 1 January 2010.

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

General Notices

The British Pharmacopoeia General Notices (Parts I, II and III) have been amended as follows.

European Pharmacopoeia

A review of the presentation, within the British Pharmacopoeia, of texts harmonised between the European Pharmacopoeia, Japanese Pharmacopoeia and United States Pharmacopeia, will be made for a future edition of the British Pharmacopoeia. In the meantime, the statement