Safeguarding public health

The British Pharmacopoeia

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OUTLINE

- Introduction
- National Activity
- European and International Activity
- Future

INTRODUCTION

- Medicines and Healthcare products Regulatory Agency (MHRA)
  - UK Government Agency for ensuring medicines and medical devices work and are acceptably safe
- BP and Laboratory Services Group
  - BP incorporated into the MHRA Trading Fund in 2003
  - Part of Inspection, Enforcement and Standards Division of MHRA
  - 19 members (16.5 BP + 1.5 Lab Services) + 1 PA
  - Publications & Reference Materials (BP; BP (Vet); British Approved Names; Electronic Updates)
  - Website
  - Management of Laboratories (BP and MHRA)
    - Evaluation & development of BP monographs; BPCRS establishment
    - Forensic work
    - Support for Regulatory activity
    - Market surveillance

    ] MHRA

BP and Laboratory Services Group (continued)

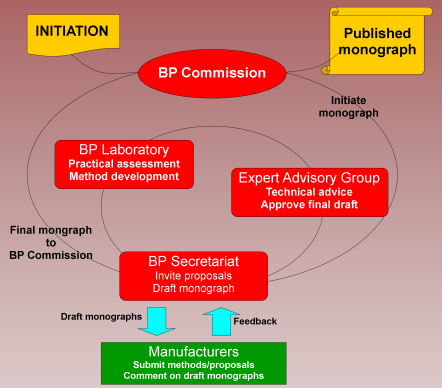
- **Websites**
  - **www.mhra.gov.uk/pharmacopoeia**
    - Information about the BP
    - News
    - BPCRS Orders
    - Forum for BPC Experts and Advisors
    - Feedback to BP Secretariat
  - **www.pharmacopoeia.co.uk**
    - BP Online
    - Sales of the BP
    - Feedback to publisher and BP Secretariat

The British Pharmacopoeia Commission

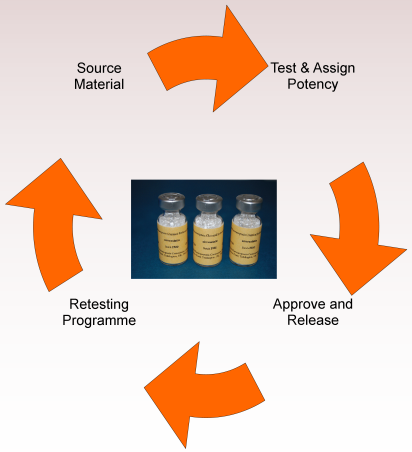
- Appointed under the Medicines Act 1968
- Preparation of the British Pharmacopoeia
- Preparation of British Approved Names
- Preparation of the British Pharmacopoeia (Veterinary)
- National pharmacopoeial authority to the European Pharmacopoeia

BP Secretariat

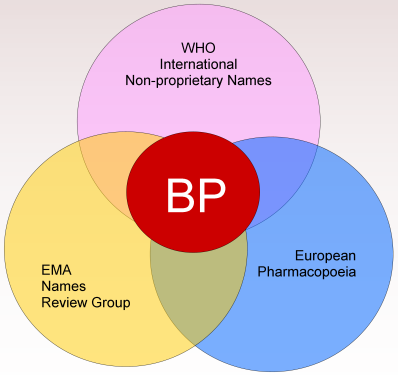
BP Monograph Development



BPCRS Reference Standards



International Activities



LEGISLATION

- Medicines Act 1968 (Section 99)
- EC Directives

  2001/83/EC (human medicines)
  2004/27/EC (amending Directive 2001/83/EC)
  2001/82/EC (veterinary medicines)
  2004/28/EC (amending Directive 2001/82/EC)
  2004/24/EC (traditional herbal medicinal products)
  2001/83/EC (homoeopathic medicines)

Regional Activity

- European Pharmacopoeia
  - National Pharmacopoeial Authority
  - Secretariat Support for the United Kingdom Delegation
  - UK Members of Groups of Experts and Working Parties

- European Medicines Agency
  - Names Review Group
    Invented names

International Activity

- **MHRA Policy**

- **World Health Organisation**
  - Group of Experts on Nomenclature
  - International Nonproprietary Names
  - Memorandum of Understanding
  - Monograph Development Collaboration

- **International harmonisation**
  - Feedback to European Pharmacopoeia

- **Chinese Pharmacopoeia**
  - Memorandum of Understanding (MHRA & SFDA)
  - Collaboration Agreement between Chinese Pharmacopoeia & British Pharmacopoeia
    - TCMs & Mutually Agreed Projects

Topics Covered in BP

Medicinal substances (Human and Veterinary)

Formulated Preparations
- General Monographs
- Specific Monographs

Biological and Biotechnological Products (Blood Products, Vaccines etc)

Radiopharmaceuticals

Surgical Materials

Herbal Medicines

Homoeopathic Preparations

Unlicensed Medicines

Veterinary Medicines

Methods of test

Supplementary information

Published Monographs

- Revision Programme
  - Medicines Act section 102 (1)

  - Targeted
  - Consequential
  - Responsive

BP Publications


PC CD
BRITISH PHARMACOPOEIA 2012 COMPLETE EDITION CD
BRITISH PHARMACOPOEIA 2012
COMPLETE EDIT
Fully searchable CD-ROM comprising
• British Pharmacopoeia 2012
• British Pharmacopoeia (Veterinary) 20
Incorporating the requirements of the 7th edi
European Pharmacopoeia as amended by Su
7.1 and 7.2
TSO
BRITISH PHARMACOPOEIA 2012
STANDARD VERSION 16.0
ISBN: 9789999108447
Data © Crown Copyright 2011
Index + Software © System Simulation Ltd
SERIAL Code
System Simulation
TSO
COMPACT disc


British Pharmacopoeia
Login to BP Online
BP 2012 - Legally effective 1 January 2011
The British Pharmacopoeia 2012: The leading global standards for UK pharmaceutical and medicinal products
Global standards:
Flexible access options:
The British Pharmacopoeia 2012 contains:
New for 2012:
Contents of BP 2012:

BP & BP (Vet) 2012

- Published August 2011
- Effective 1 January 2012
- 35 new BP monographs
- Integrates Ph Eur monographs
- 3 In-year Electronic Updates
- Available in Book and Electronic Formats

Looking Ahead

- Annual BP and BP (Vet) Publication
- British Approved Names Supplements
- Increase in New Formulated Preparation Monographs (licensed and unlicensed)
- Supplementary Chapters for BP and BP (Vet)
- Red Tape Challenge
- European Pharmacopoeia (Expertise; Advice; Comments on drafts; Laboratory support; UK Government support)
- International Collaboration
- Stakeholder Co-operation (manufacturers; practitioners; pharmacies etc)
- Website www.mhra.gov.uk/pharmacopoeia
- Tailored Publications
- Feedback

Future Strategy for World Pharmacopoeias

Working together

- Acknowledge roles of National Authority
- Acknowledge regional roles
- Acknowledge commercial activity

Thank you

Any Questions?