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
BP and Laboratory Services Group (continued)

- **Websites**
  - [www.mhra.gov.uk/pharmacopoeia](http://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](http://www.pharmacopoeia.co.uk)
    - BP Online
    - Sales of the BP
    - Feedback to publisher and BP Secretariat
LEGISLATION

- Medicines Act 1968 (Section 99)
- EC Directives
  - 2001/83/EC (human medicines)
  - 2001/82/EC (veterinary medicines)
  - 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
Safeguarding public health

**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
Safeguarding public health

British Pharmacopoeia
M Vallender 29 February 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
Safeguarding public health

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?