**Medicines and Healthcare products Regulatory Agency**

# HUMAN MEDICINES REGULATIONS 2012
# ADVISORY BODIES ANNUAL REPORT 2013

**Presented to Parliament pursuant to Part 2, Section 12 (2) of the Human Medicines Regulations 2012**

Commission on Human Medicines

British Pharmacopoeia Commission

**Contact for information about these reports:**
**Fay Norris**
**151 Buckingham Palace Road**
**020 3080 6060**


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**Any enquiries regarding this publication should be sent to the MHRA at:**

**Medicines and Healthcare products Regulatory Agency**
**Information Services**
**151 Buckingham Palace Road**
**London SW1W 9SZ**
**020 3080 6000**

**E-mail: info@mhra.gsi.gov.uk**

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# FOREWORD BY THE PARLIAMENTARY UNDER SECRETARY OF STATE FOR QUALITY

It gives me great pleasure to present the Annual Reports for 2013 of the Human Medicines Regulations Advisory Bodies: the Commission on Human Medicines and the British Pharmacopoeia Commission. These reports include a record of Members' interests in the pharmaceutical industry and code of practice.

On behalf of all Health Ministers I would like to thank the Chairmen and Members of all the Expert Committees whose professional expertise, commitment and hard work plays a vital role in ensuring that the medicines we take continue to meet the highest standards of safety, quality and efficacy.

The Earl Howe

# COMMISSION ON HUMAN MEDICINES ANNUAL REPORT 2013

## TERMS OF REFERENCE

1. The Commission on Human Medicines was established in October 2005. Its functions are set out in regulation 10 of the Human Medicines Regulations 2012 (SI 2012/1916).

2. The functions of the Commission on Human Medicines are:

    - to advise the Health Ministers and the Licensing Authority (LA) on matters relating to human medicinal products including giving advice in relation to the safety, quality and efficacy of human medicinal products where either the Commission thinks it appropriate or where it is asked to do so;

    - to consider those applications that lead to LA action as appropriate (i.e. where the LA has a statutory duty to refer or chooses to do so);

    - to consider representations made (either in writing or at a hearing) by an applicant or by a licence or marketing authorisation holder in certain circumstances;

    - to promote the collection and investigation of information relating to adverse reactions to human medicines for the purposes of enabling such advice to be given.

      The Commission is similarly involved in respect of medicinal products to which relevant EC legislation applies.

## APPOINTMENTS

3. In February 2013, the Secretary of State for Health appointed a new Chairman to the Commission:

   **Professor Stuart Ralston** MB ChB MD FRCP FMedSci FRSE
   Arthritis Research UK Professor of Rheumatology, University of Edinburgh, Western General Hospital, Edinburgh.

4. In January 2013, the following re-appointments to the Commission were made:

   **Professor Deborah Ashby** OBE BSc MSc PhD CStat Hon. MFPHM Hon. MRCR FMedSci
   Professor of Medical Statistics and Clinical Trials Co-Director of Imperial Clinical Trials Unit, School of Public Health, Imperial College London

   **Mrs Alison Bowser**
   Lay Representative. Patient and Public Involvement Officer, Research Design Service, Southampton University & National Institute for Health Research

**Professor Janet H Darbyshire** CBE MB ChB FMedSci FRCP FFPH FRSS (Hon)
Emeritus Professor of Epidemiology, University College London

**Ms Amanda Hoey**
Lay Representative. Director, Consumer Health Consulting Ltd

**Professor Ian V D Weller** BSc MB BS MD FRCP Hon FRCP (Glas)
Emeritus Professor of Sexually Transmitted Diseases, University College London Medical School.

5. Details of Commissioners' re-appointment dates can be found at **Appendix I**.

6. The Commission also appointed and re-appointed members to its Expert Advisory Groups (EAGs). The details are listed at **Appendix II**.

## MEMBERSHIP

7. Commissioners' details are listed at **Appendix I**. There are currently 11 EAGs that report to the Commission, their remits and membership are listed at **Appendix II**.

8. The Commission warmly congratulates **Dr Barbara A Bannister**, Chair of the Anti Infectives, HIV/AIDS and Hepatology EAG, on receiving an MBE in the Queen's Birthday Honours.

9. The Commission warmly congratulates **Professor Andrew Hall**, retired member of the former Biologicals and Vaccines EAG, on receiving a knighthood in the Queen's Birthday Honours.

10. The Commission warmly congratulates **Professor Peng T Khaw**, member of the Ophthalmic Panel, on receiving a knighthood in the Queen's Birthday Honours.

11. In April, the Commission conducted a review of its Biologicals and Vaccines and Clinical Trials Expert Advisory Groups. The Commission concluded that the EAGs should be merged in order to best utilise expertise across the groups. This resulted in the formation of the Clinical Trials, Biologicals & Vaccines Expert Advisory Group.

12. The National Institute for Biological Standards and Control (NIBSC), previously part of the Health Protection Agency (HPA), became a centre of the Medicines and Healthcare Products Regulatory Agency alongside the Clinical Practice Research Datalink (CPRD) on the 1st April 2013. As a consequence of this, employees of NIBSC became employees of the Medicines and Healthcare Products Regulatory Agency and as such were no longer able to remain as members of CHM or its Expert Advisory Groups.

13. The Commission wishes to record its gratitude and appreciation of the valuable work of its Expert Advisory Groups and Working Groups listed below. Members' details are listed at **Appendix II**.

**Expert Advisory Groups 2013**

Anti-Infectives, HIV/AIDS and Hepatology (AIHHEAG)
Chaired by **Dr Barbara A Bannister MBE**

Biologicals and Vaccines (BVEAG) (until 17 April 2013)
Chaired by **Dr Angela E Thomas**

Cardiovascular, Diabetes, Renal, Respiratory and Allergy (CDRRAEAG)
Chaired by **Dr J Colin Forfar**

Chemistry, Pharmacy and Standards (CPSEAG)
Chaired by **Professor Derek H Calam** (until 15 October 2013)
Chaired by **Professor Kevin M G Taylor** (from 15 October 2013)

Clinical Trials (CTEAG) (until 17 April 2013)
Chaired by **Professor Sir Robert Lechler** (until 05 March 2013)

Clinical Trials, Biologicals & Vaccines (CTBVEAG)
Chaired by **Dr Angela E Thomas** (from 18 April 2013)

Gastroenterology, Rheumatology, Immunology & Dermatology (GRIDEAG)
Chaired by **Professor Stuart Ralston** (until 11 February 2013)
Chaired by **Professor Anthony G Wilson** (from 23 May 2013)

Medicines for Women's Health (MWHEAG)
Chaired by **Dr Ailsa Gebbie**

Neurology, Pain & Psychiatry (NPPEAG)
Chaired by **Professor David G C Owens** (from 18 April 2013)

Oncology and Haematology (OHEAG)
Chaired by **Professor John Smyth** (until 18 July 2013)
Chaired by **Dr Angela E Thomas** (from 19 July 2013)

Paediatric Medicines (PMEAG)
Chaired by **Professor Rosalind L Smyth**

Patient and Public Engagement (PPEEAG)
Chaired by **Mr Harry Cayton OBE**

Pharmacovigilance (PEAG)
Chaired by **Professor Munir Pirmohamed**

**Working Groups 2013**

Dianette Working Group
Chaired by **Dr Ailsa Gebbie**

Insulins Working Group
Chaired by **Dr Amanda Adler**

National Emergency Stockpile Quality Panel
Chaired by **Professor Stuart Ralston**

Nicotine Containing Products Working Group
Chaired by **Professor Ian V D Weller**

Review of Non-Prescription Analgesics Working Group
Chaired by **Professor Stuart Ralston**

14. The Committee for Medicinal Products for Human Use (CHMP) is the medicines regulatory committee for all EU member states.

    The Commission notes with great pleasure the extent of its influence within the CHMP's Scientific Advisory Groups. Professor Ian V D Weller is Vice-Chair of the HIV/Viral Diseases SAG and Dr Barbara Bannister, standing invited expert to the Commission, is Chair of the Anti-Infectives SAG.

15. Commissioners and EAG members serving as SAG members are as follows:

    - Professor Robert C Read (Anti-Infectives)
    - Professor Deborah Ashby (Cardiovascular Issues)
    - Dr J Colin Forfar (Cardiovascular Issues)
    - Dr Susan Benbow (Diabetes/Endocrinology)
    - Professor Deenan Pillay (HIV/Viral Diseases)
    - Dr Anthony Johnson (Neurology)
    - Professor Martin Rossor (Neurology)
    - Professor David G C Owens (Psychiatry)
    - Professor Elizabeth Miller (Vaccines).

16. Professor Derek H Calam retired from CHM and as Chair of the CPSEAG in October. The Commission extends its sincerest gratitude to Professor Calam for his valuable and very long-standing contribution to its work and that of its EAGs, and to CHM's predecessor, the Committee on Safety of Medicines (CSM) and its subcommittees. His total service has spanned over 38 years. Professor Calam will continue as a member of CPSEAG and CTBVEAG until October 2014.

17. Professor John Smyth retired from his role as Chair of the OHEAG in July. The Commission wishes to extend its thanks to Professor Smyth for his valuable and very long-standing contribution to the work of CHM, CSM and its subcommittees, which spanned over 29 years in total.

18. Professor Rosalind Smyth stepped down from CHM and as Chair of PMEAG in December. The Commission wishes to extend its thanks to Professor Smyth for her valued contribution to the work of CHM, PMEAG and the CSM's Paediatric Medicines Working Group, which spanned over 13 years in total.

19. The Commission wishes to record its gratitude to those members of its External Expert Panel and Ophthalmic Panel who attended meetings or provided written advice to the Commission and its Expert Advisory Groups during the course of the year. Members' details are listed at the end of this report at **Appendix III**.

## MEETINGS

20. The Commission held 11 meetings during 2013. Two day meetings were held in February, May, June and September. One day meetings normally lasted between

five and six hours. Meetings were held at the Medicines and Healthcare Products Regulatory Agency, 151 Buckingham Palace Road, London, SW1W 9SZ.

## SECRETARIAT

21. The Commission's secretariat is based at the MHRA. A list of the support staff is at **Appendix IV**. The Commission also wishes to place on record its indebtedness and gratitude to the excellent professional and administrative staff of the MHRA concerned with the business of the Commission and its Expert Advisory Groups.

## COSTS

22. Commissioners are entitled to claim an attendance fee of £325 per day (Chairman's fee £500). Expert Advisory Groups members are entitled to claim an attendance fee of £200 (Chairman's fee £325). Travel and subsistence is also payable within Department of Health guidelines.

## FIRST CONSIDERATION BY THE COMMISSION

23. The Commission considered and advised on a total of 121 applications for marketing authorisations. The table below shows the outcome for national/mutual recognition/decentralised/centralised applications for new active substances and abridged applications at first consideration (i.e. before appeals).

**Commission Advice on Applications for National Marketing Authorisations/Mutual Recognition/Decentralised and Centralised Applications**

| | **Grant advised** | **Grant not advised** |
|---|---|---|
| **New Active Substances** | **5** | **46** |
| **Abridged Applications** | **11** | **59** |

24. The Commission was extensively involved in applications made through the European centralised procedure. The Commission considered 45 new active substances, or new combinations of active substances, authorised through the Centralised Procedure.

## APPEALS

25. The Commission considered a total of five pre-hearings covering 13 applications. Of these, one pre-hearing covering two applications was approved at the pre-hearing stage, provided the product particulars were amended. One pre-hearing covering one application was withdrawn. One pre-hearing covering two

applications was not approved and proceeded to a second pre-hearing before receiving an oral hearing. Following the oral hearing, one application was approved, provided that the product particulars were amended. The other application was not approved. For the remaining pre-hearing (covering four applications), a hearing is scheduled for January 2014.

26. In July, the Commission considered one hearing covering eight applications and advised that the marketing authorisations should be withdrawn as an interim measure until a final European position is adopted.

27. The Commission considered an average of 11 applications at each of its 11 meetings in 2013, in addition to clinical trial applications, appeals, reclassifications, pharmacovigilance issues and other matters.

## EXTERNAL STAKEHOLDERS

28. The Commission received the following as observers:

**Miss Derry Begho**
Campaigns Assistant, Policy and Public Affairs, Asthma UK

**Professor Philip Conaghan**
Guideline Development Group Chair

**Mr Ben Doak**
Guideline Commissioning Manager, National Institute of Clinical Excellence

**Ms Susan Grieve**
Principal Pharmacist, Department of Health

**Ms Susan Latchem**
Operations Director, National Clinical Guideline Centre

**Dr Stephen McWilliam** BA (Oxon) MBBS MRCPCH
MRC Clinical Pharmacology and Therapeutics research Fellow, University of Liverpool

**Ms Vanessa Nunes**
Guideline Lead and Senior Research Fellow, National Clinical Guideline Centre

**Ms Patricia Parris**
Policy Officer, Department of Health

**Mrs Bronwen Thompson**
Formerly Asthma Respiratory Team, Department of Health

**Dr Lauren Walker** BSc (Hons) MBChB (Hons) MRCP (UK)
MRC Clinical Pharmacology and Therapeutics research Fellow, University of Liverpool

**Dr Vincent Yip** MSc PhD FBTS ERT FHEA
MRC Clinical Pharmacology and Therapeutics Research Fellow, University of Liverpool

## CONSIDERATION OF OTHER MATTERS

29. In addition to the consideration of applications and appeals, the Commission also considered the safety of marketed medicines and advised on matters of medical and pharmaceutical relevance as follows:

## SAFETY OF MARKETED MEDICINES

### Metoclopramide and neurological adverse effects

30. The Commission considered an assessment of the balance of risks and benefits of metoclopramide-containing medicinal products in the context of a Europe-wide review. Metoclopramide is used for the treatment and prevention of nausea and vomiting including post-operative and chemotherapy-induced nausea and vomiting.

31. The review had been triggered because of long-standing concerns in France about the safety of metoclopramide, particularly with regard to the use of the liquid oral formulation in children and neurological adverse reactions (in particular extrapyramidal disorders and tardive dyskinesia).

32. The Commission concluded that neurological adverse effects of metoclopramide are well established. The key safety concerns which were already recognised related to: concentrated oral liquid formulations, particularly when used in children; prolonged use in chronic indications; and high doses in prevention of acute chemotherapy-induced nausea and vomiting.

33. In relation to use in children, the Commission concluded that the established risks could be managed by restricted second line indications in specialist settings, clear and restricted dosing instructions, appropriate formulations and measuring devices, and updated product information. An article was published in the August 2013 edition of Drug Safety Update[1].

### Intravenous iron-containing medicinal products and hypersensitivity reactions

34. The Commission considered assessments of the safety of intravenous (IV) iron-containing medicinal products in the context of a Europe-wide review which was triggered following concerns about the risk of serious hypersensitivity reactions and concerns that the level of risk may be different with different products.

35. The Commission advised that the spontaneous reporting rates of serious hypersensitivity reactions were very low and that it was not possible to clearly differentiate the risk between products on the basis of the available data.

36. The Commission advised that the balance of benefits and risks for all the iron-containing IV products remained positive and that risk minimisation measures in the Summaries of Product Characteristics (SmPCs) should be consistent across products.

37. The Commission advised that further investigation was required in relation to the mechanism underlying the hypersensitivity reactions, whether different rates and methods of administration may influence the risk of adverse reactions and the

[1] (www.mhra.gov.uk/drugsafetyupdate)

clinical utility of a test dose in minimising risk. An article was published in the August 2013 edition of Drug Safety Update.

**Co-cyprindiol (cyproterone acetate/ethinyloestradiol) and risk of venous thromboembolism**

38. The Commission considered an assessment of the balance of risks and benefits of co-cyprindiol (cyproterone acetate/ethinyloestradiol) which is used in the treatment of severe acne or moderately severe hirsutism where other treatments have failed. A Europe–wide review of the risks and benefits of co-cyprindiol had been initiated following concerns in France about risk of venous thromboembolism (VTE) particularly in association with off-label contraceptive use.

39. The Commission was advised by an ad hoc Expert Group of dermatologists, gynaecologists, GPs endocrinologists and patient representatives. The Commission advised that the balance of risks and benefits for co-cyprindiol in its authorised indications was positive. The Commission advised that the risk of VTE particularly in association with off-label contraceptive use could potentially be reduced by ensuring the product information across the EU included appropriate warnings and advice about its contraceptive action and that use in women over the age of 50 years and concomitant use of hormonal contraception should be contraindicated. An article was published in the June 2013 edition of Drug Safety Update.

**Hydroxyethyl starch solutions and risk of renal injury and increased mortality**

40. The Commission considered an assessment of the balance of risks and benefits of hydroxyethyl starch (HES) solutions which are used as fluid replacement in hypovolaemia and hypovolaemic shock. The risks and benefits of HES had been the subject of a Europe-wide review following the publication of studies[2,3,4] which suggested an increased risk of renal injury and death in patients treated with HES compared with crystalloids (salt solutions).

41. On 13 June the European Medicines Agency's (EMA's) Pharmacovigilance Risk Assessment Committee (PRAC) recommended that the benefits of infusion solutions containing HES no longer outweighed the risks, in particular the increased risk of renal injury and increased mortality compared with crystalloids.

42. On 21 June the Commission advised that on the basis of the available evidence the benefit-risk balance for HES was negative in all patient groups and indications, and advised the Licensing Authority to suspend the marketing authorisations for HES in the UK and to withdraw the products as an interim measure until a final European position was adopted. An article was published in the June 2013 edition of Drug Safety Update[1] and a message was sent to healthcare professionals through the Central Alerting System.

43. The final conclusion of the Europe-wide review was that HES must no longer be used to treat patients with sepsis or burns injuries or critically ill patients because of an increased risk of kidney injury and mortality, but that HES solutions may continue to be used in patients to treat hypovolaemia caused by acute blood loss,

[2] Brunkhorst F, et al. N Engl J Med 2008; 358: 125–391
[3] Perner A, et al. N Engl J Med 2012; 367: 124–34
[4] Myburgh J, et al. N Engl J Med 2012; 367: 1901–11

where treatment with alternative solutions (crystalloids) alone is not considered to be sufficient. To minimise risk in these patients HES should not be used for more than 24 hours and patients' kidney function should be monitored after HES administration. The review also concluded that additional studies should be carried out on the use of HES in elective surgery and trauma patients.

**Strontium ranelate (Protelos/Osseor) and increased cardiovascular risk**

44. The Commission considered assessments of the balance of risks and benefits of strontium ranelate (Protelos/Osseor) which is used in the treatment of osteoporosis. This was in the context of a Europe-wide review which was triggered following concerns about increased cardiovascular risk identified in an analysis of randomised controlled clinical trials.

45. Following an initial assessment in April, an article was published in Drug Safety Update[1] to inform healthcare professionals of restrictions to the use of strontium ranelate pending a full assessment of the risks and benefits.

46. In December, the Commission considered a comprehensive assessment of the available evidence and advised that the balance of risks and benefits for strontium ranelate remained favourable if used under specialist supervision as a last line therapy and contraindicated in those with cardiovascular disease.

47. In February 2014, the Europe-wide review concluded that the balance of risks and benefits could be considered to remain positive subject to the introduction of additional risk minimisation measures that included further revisions to the indications to restrict its use in severe osteoporosis in patients for whom the use of other osteoporosis treatments is not possible, strengthened warnings on cardiovascular risk and the requirement for monitoring of cardiovascular risk on a regular basis generally every 6 to 12 months. The need for a study of robust design to examine drug utilisation and measure the effectiveness of risk minimisation was also required.

**Short-acting beta agonists and cardiovascular risk in tocolysis and other obstetric conditions**

48. The Commission considered an assessment of the risks and benefits of short acting beta agonists (SABAs, salbutamol and terbutaline) in obstetric indications including tocolysis. This was in the context of a Europe-wide review which was initiated following concerns about their efficacy and that they were associated with cardiovascular adverse effects in the mother and baby.

49. The Commission concluded that the intravenous formulation was only efficacious for short term use with appropriate patient monitoring.

50. The Commission concluded that the risks associated with oral or suppository SABA formulations used in tocolysis outweighed any benefit and recommended that the obstetric indication of tocolysis should be removed from these formulations. An article was published in the November edition of Drug Safety Update.

**Paracetamol and review of safety profile**

51. The Commission considered a review of signals associated with long-term use of paracetamol in osteoarthritis. The Commission advised that the observational

studies presented were insufficient to establish a causal association between renal, cardiovascular and serious gastrointestinal adverse effects and long-term paracetamol use.

52. The Commission was concerned about the detrimental impact on public health as a result of unnecessary switching from paracetamol to non-steroidal anti-inflammatory drugs (NSAIDs) or opioids.

53. The Commission advised that on the basis of the data presented, the balance of risks and benefit for paracetamol for the management of osteoarthritis remained positive and no regulatory action was warranted.

54. The Commission advised that the risks and benefits and appropriate use of over the counter (OTC) paracetamol should be further reviewed and agreed that an ad hoc expert group should be set up.

**Diclofenac as a pharmacy medicine and cardiovascular risk**

55. The Commission considered a paper discussing the appropriate risk management and availability of oral diclofenac as a pharmacy medicine following the outcome of a Europe-wide review which concluded that the cardiovascular risks associated with diclofenac are greater than those for other NSAIDs and similar to those for selective COX-2 inhibitors.

56. The marketing authorisations for diclofenac were amended in September 2013 to include contraindications in patients with established cardiovascular risk and it was advised that measures should be taken to strengthen the risk minimisation of oral diclofenac as a pharmacy medicine.

57. The Commission agreed to public consultation on its legal classification. The outcome of the public consultation on this issue will be considered by the working group being brought together to review non-prescription analgesics (see below).

**Combined hormonal contraceptives and risk of VTE and arterial thromboembolism**

58. The Commission considered an assessment of the risks of VTE and arterial thromboembolism (ATE) associated with combined hormonal contraceptives (CHCs). This was in the context of a Europe-wide review initiated by France following concerns that risk of VTE associated with CHCs containing some “3rd and 4th generation” progestogens is higher than the risk of VTE with CHCs containing levonorgestrel.

59. The Commission considered advice from the Medicines for Women’s Health Expert Advisory Group. The Commission advised that the efficacy of CHCs in pregnancy prevention was well established and there was robust evidence to support additional long term benefits of CHC use in reduced incidence of endometrial and ovarian cancer and overall mortality.

60. The Commission advised that the risk of VTE with all CHCs was small and while there was good evidence that the risk of VTE may vary between products depending on the progestogen, the benefits of all CHCs outweigh the risks.

61. The Commission advised that there was no good evidence that the small increased risk of ATE associated with CHCs differed depending on the

progestogen. An article was published in the February 2014 edition of Drug Safety Update and a message was sent to healthcare professionals through the Central Alerting System.

**Incretin-based medicines and risk of pancreatitis and pancreatic cancer**

62. The Commission considered an assessment of a signal of pancreatitis and pancreatic cancer in patients with Type 2 diabetes mellitus (T2DM) treated with incretin-based medicines (including glucagon-like peptide-1 agonists and dipeptidylpeptidase-4 inhibitors). This was in the context of a Europe-wide review triggered by the publication[5] of a histopathology study which described findings from pancreatic tissue samples obtained from diabetic patients with brain death undergoing organ harvest.

63. The Commission advised that an association between incretin-based drugs and pancreatitis was plausible but the available data suggested it was a very rare adverse effect. The Commission advised that an association between incretin-based medicines and chronic pancreatitis potentially predisposing to increased cancer risk should be further elucidated.

64. The advice of the Commission informed the UK position in discussions at the Committee for Medicinal Products for Human Use (CHMP) which concluded that review of the available data had not identified a new safety issue with these medicines, however there were still uncertainties about their long term pancreatic safety. CHMP concluded that marketing authorisation holders should study further the pancreatic safety of their products and warnings about pancreatitis in SmPCs should be harmonised. The conclusion of the Europe-wide review was published in August 2013 on the website of the EMA.[6]

**COSOPT (dorzolamide hydrochloride, timolol maleate) preservative-free single dose eye drops and reports of eye injury**

65. The Commission considered an assessment of complaints and reports of eye injury received in association with a newly introduced container (Catalent for the combination product containing dorzolamide hydrochloride and timolol maleate) with wings at the same level as the dropper tip.

66. The Commission also considered evidence from patient reports that the shape of the container caused the volume and direction of droplet release to be altered in a manner that impacted on dose delivery and compliance.

67. The Commission advised the product should be withdrawn from the market, subject to confirmation that there were adequate supplies of appropriate and acceptable alternatives.

68. Subsequent investigations established that withdrawal of the Catalent Cosopt product would result in inadequate supplies of preservative free eye drops to meet patient demand.

69. The Commission was therefore informed that the Licensing Authority was acting to enable the marketing authorisation holder to supply an alternative Catalent

[5] Butler et al, Diabetes. 2013 Jul; 62 (7): 2595-604
[6] http://www.ema.europa.eu/docs/en_GB/document_library/Report/2013/08/WC500147026.pdf

variant as an interim measure. An article was published in the December 2013 edition of Drug Safety Update[1].

## MEDICINES AVAILABLE WITHOUT PRESCRIPTION

### Reclassification of medicines from POM to P and P to GSL

70. The Commission considered five applications for change of legal status during the year. Three were for medicines for General Sales List (GSL) availability. The Commission advised that two of the applications might be approvable. Public consultation is under way for one of the products:

    - ibuprofen lysine 400mg oral powder sachets for the symptomatic relief of mild to moderate pain associated with headache, migraine, backache, period pain, dental pain, rheumatic and muscular pain, and cold and flu symptoms such as sore throat and fever.

71. The Commission advised against one application for GSL availability.

72. Two applications were for Prescription Only Medicine (POM) to Pharmacy Only (P) reclassification. One was for reclassification through the centralised procedure for which the Commission advised against P availability. The Commission advised that one application might be approvable and recommended that public consultation could take place.

### Omeprazole - Impact of European harmonised SmPC on CHM advice for Pharmacy availability

73. The Commission considered a paper on the impact of EU harmonisation of the SmPC for omeprazole on its previous decisions for pharmacy availability of omeprazole in the UK. The EU harmonised SmPC differed from the UK product information based on CHM advice for P omeprazole in two key areas:

    - Firstly, the harmonised posology was 20mg daily for up to 14 days, whilst the dosage based on CHM advice included advice to cut down to 10mg daily if this was adequate to control symptoms and allowed up to 28 days treatment.

    - Secondly, the harmonised SmPC stated that patients aged over 55 years were advised to consult their doctor or pharmacist if they need regular treatment for their symptoms of heartburn whilst the age limit based on CHM advice was 45 years.

74. The Commission advised that the differences were not considered to represent a major safety concern. The warning in the EU harmonised SmPC to advise patients over 55 years to see their doctor if they need regular treatment for their symptoms was consistent with NICE guidance. A 20mg dose was more effective than a 10mg dose and the safety profiles of the two doses were similar. A standard 20mg dose would not be a concern for short-term non-prescription treatment and a 20mg dosage for non-prescription use would help to avoid confusion for patients.

## THE COMMISSION'S EXPERT ADVISORY GROUPS AND WORKING GROUPS

75. The remit and membership of the Expert Advisory Groups and Working Groups are listed in **Appendix II**.

### Anti-Infectives, HIV/AIDS and Hepatology Expert Advisory Group (AIHHEAG)

76. The Anti-Infectives, HIV/AIDS and Hepatology EAG did not meet during 2013. EAG members provided written comments and advice on seven items.

77. In May, the Chair provided written comments on a paper discussing the association of cardiovascular mortality with the use of clarithromycin.

78. In August, the EAG provided written comments on:

- two medicines for the short term treatment of mild to moderate bacterial skin infections
- a medicine for the prevention of sepsis[7] in surgical procedures and open wounds
- a medicine for the treatment of chronic hepatitis C[8]
- a medicine for the treatment of the prolonged inflammation of the liver, known as chronic hepatitis.

79. In September, the Chair provided written comments on:

- a paper discussing the cardiovascular risk and risk of sudden death with azithromycin[9]
- a paper on the association of cardiovascular mortality with the use of clarithromycin.

80. In October, the EAG provided written comments on a paper discussing the increased risk of Varicella-associated serious skin and soft tissue complications following the use of ibuprofen.

81. In November, the EAG provided written comments on a medicine to treat adults infected by Human Immunodeficiency Virus (HIV).

### Biologicals and Vaccines Expert Advisory Group (BVEAG)
**(1 January to 17 April 2013)**

82. Prior to merging with the CTEAG, the BVEAG met on one occasion in 2013 and provided written comments and advice on two items.

83. In January, the EAG provided written comments on a vaccine used for prophylaxis[10] of influenza in individuals.

84. In March, the EAG convened and made recommendations on:

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[7] a life-threatening illness caused by the body overreacting to an infection
[8] a viral infection of the liver in adults
[9] azithromycin is a macrolide antibiotic used to treat a variety of infections caused by bacteria and micro-organisms including chest, throat and nasal infections, ear infections, skin and soft tissue infections and sexually transmitted diseases caused by Chlamydia
[10] a preventative treatment

- a medicine for use in fertility treatment
- a medicine for the treatment of haemophilia A[11].

85. In April, the EAG provided written comments on a medicine for the treatment of cartilage defects of the joints.

**Clinical Trials Expert Advisory Group (CTEAG)**
**(1 January to 17 April 2013)**

86. Prior to merging with the BVEAG, the CTEAG met on two occasions, provided advice by written correspondence on two items and held one clarification meeting.

87. In February, the EAG convened and made recommendations to the Commission on:

- a clinical trial application for a medicine proposed for use in the treatment of acute wet age-related macular degeneration[12]
- a clinical trial application for a medicine indicated for the treatment of squamous cell carcinoma[13] of head and neck
- a medicine for the treatment of rheumatoid arthritis, psoriasis, inflammatory bowel disease and transplantation
- a clinical trial application for a medicine indicated for the treatment of critical limb ischaemia[14]
- a clinical trial application for a medicine indicated for the treatment of ischaemic stroke[15].

88. In March, the EAG provided written comments on a clinical trial application for a medicine for the treatment of Netherton's Syndrome[16].

89. In addition, members of the EAG took part in a clarification meeting on a clinical trial application for a medicine proposed for use in the treatment of acute wet age-related macular degeneration.

90. In April, the EAG convened and made recommendations to the Commission on:

- a medicine proposed for use in the treatment of acute wet age-related macular degeneration
- a medicine for the treatment of Netherton's syndrome.

[11] a bleeding disorder caused by deficiency of clotting factor 8
[12] an eye condition that develops quickly and affects a tiny part of the retina at the back of the eye, called the macula
[13] a type of cancer which usually originates in the squamous cells that like the moist surfaces inside the head and neck
[14] a severe obstruction of the arteries which markedly reduces blood flow to the extremities (hands, feet and legs)
[15] a physical blockage of blood flow to an area of the brain, causing brain cells in the area to die. Ischaemic stroke cause permanent brain damage and long term impairments
[16] a rare skin condition which is characterised by dry, thickened and rough skin, and short brittle hair

**Clinical Trials, Biologicals & Vaccines Expert Advisory Group (CTBVEAG)**
**(18 April to 31 December 2013)**

91. The CTBVEAG met four times and provided advice by written correspondence on three items.

92. In May, the EAG convened and made recommendations on:

- a clinical trial application for a medicine indicated for the treatment of cancer of the oesophagus[17]
- a clinical trial application for a medicine indicated for the treatment of haemophagocytic lymphohistiocytosis[18]
- a medicine for the treatment of acute heart failure[19] in adult patients.

93. In June, the EAG convened and made recommendations on:

- a medicine for the preventive use in premature neonates with a higher risk of respiratory distress syndrome (RDS)[20]
- a medicine to treat the signs and symptoms of moderately to severely active ulcerative colitis[21], and moderately to severely active Crohn's disease[22]
- a paper on the National Immunisation Programme 2013/2014 – Strengthening Vaccine Pharmacovigilance.

94. In July, the EAG convened and made recommendations to the Commission on:

- a medicine proposed for use in adults to repair the surface of the eye when it has been badly damaged by injury
- a medicine proposed for use to lower blood glucose in adults with type 2 diabetes mellitus[23]
- a medicine proposed for the use of vaccine for protection against influenza (flu)
- a clinical trial application for a medicine proposed for the prevention of organ rejection by patients receiving a liver transplant.

95. In July, the EAG provided written comments on a medicine proposed to reduce the duration of neutropenia[24] and the occurrence of febrile neutropenia[25].

96. In September, the EAG convened and made recommendations to the Commission on:

[17] the tube through which food passes from the throat to the stomach
[18] a disorder in which the immune system produces too many active immune cells. Over-activation of the immune system causes fever and damages the liver and spleen, resulting in the enlargement of these organs
[19] a condition in which the heart cannot pump enough blood to meet the requirements of the body tissue
[20] a serious medical condition in which a newborn baby's lungs cannot provide their body with enough oxygen
[21] inflammatory disease of the large bowel
[22] inflammatory disease of the gastrointestinal tract
[23] a condition causing the body not to produce enough insulin to function properly
[24] low white blood cell count
[25] low white blood cell count with a fever

- a medicine proposed for use to control blood sugar levels in adults with type 2 diabetes mellitus
- a medicine to treat diabetes mellitus in adults and children
- a medicine for the treatment of Morquio syndrome[26]
- a clinical trial application for a medicine indicated for the prevention of organ rejection by patients receiving a liver transplant
- a paper presenting the review of a possible link between etanercept and certain types of brain cancer.

97. In October, the EAG provided written comments on a medicine for the treatment of Multiple Sclerosis (MS)[27].

98. In November, the EAG provided written comments on a clinical trial application for a medicine for the treatment of Childhood Cerebral Adrenoleukodystrophy[28]. The condition is also known as "ALD" or "Schilder's disease".

**Cardiovascular, Diabetes, Renal, Respiratory and Allergy Expert Advisory Group (CDRRAEAG)**

99. The CDRRAEAG met on two occasions and considered and advised on applications for new products, pre-hearings, variations, new signals, risk assessments and guidelines. In addition the EAG provided advice by written correspondence on 16 occasions.

100. In January, the EAG provided written comments on:

- a medicine used as an adjunct to a low-fat diet and other lipid[29]-lowering medicinal products
- a medicine for the treatment of patients with cystic fibrosis to treat lung infections caused by Pseudomonas aeruginosa[30]
- a medicine to make breathing easier for adult patients suffering from a lung disease called chronic obstructive pulmonary disease (COPD)[31]
- a proposal for the harmonisation of the product information for 3 medicines used for the prevention of venous thromboembolism[32] following hip or knee replacement surgery in adults
- a medicine used in the treatment of angina[33].

[26] an inherited disease of metabolism in which the body is missing or does not have enough of a substance to break down long chains of sugar molecules
[27] a disease affecting the nerves in the brain and spinal cord, causing problems with muscle movement, balance and vision
[28] rapidly advancing global neurological decline (onset in childhood, affecting both physical and intellectual abilities) caused by accumulation of long-chain fatty acids
[29] a group of naturally occurring molecules that include fats, waxes, sterols, fat-soluble vitamins (such as vitamins A, D, E, and K), monoglycerides, diglycerides, triglycerides, phospholipids, and others
[30] a bacterium that frequently infects the lungs of cystic fibrosis patients at some time during their lives. If the infection is not properly treated, it will continue to damage the lungs, causing further problems to breathing
[31] the name for a collection of lung diseases including chronic bronchitis, emphysema and chronic obstructive airways disease
[32] a blood clot in the vein
[33] chest pain caused by a restriction of blood to the heart muscle

101. In March, the EAG Chair discussed, with invited experts via teleconference, and made recommendations on a medicine for the treatment of familial hypercholesterolaemia[34].

102. In March, the EAG also provided written comments on a medicine for the treatment of COPD.

103. In April, the EAG provided written comments on a medicine for the treatment of adult patients with COPD.

104. In May, the EAG discussed and made recommendations on a medicine for the treatment of acute heart failure in adult patients.

    The EAG also considered and discussed:

    - the balance of risks and benefits of a medicine for the treatment of various hypertensive crisis, controlled hypertension during anaesthesia and peri-operative[35] hypertension
    - the cardiac safety of a medicine used in nausea and vomiting, gastrointestinal reflux and upper abdominal discomfort.

105. In May, the EAG provided written comments on a medicine to control blood sugar levels of adult patients with type 2 diabetes mellitus.

106. In June, the EAG provided written comments on a medicine for the treatment of iron deficiency anaemia.

107. In July, the EAG provided written comments on:

    - a medicine for the treatment of severe croup[36] in children and adolescents aged 6 months to 14 years
    - a medicine for the treatment of adult patients with type 2 diabetes
    - Glucagon-like peptide-1 (GLP-1)[37] based therapies and risks of pancreatitis and pancreatic cancer.

108. In August, the EAG provided written comments on a medicine for the treatment of patients with COPD.

109. In September, the EAG provided written comments on:

    - a proposal that schools hold supplies of asthma inhalers for emergency use
    - the risk of sudden cardiac death associated with a medicine used in the treatment of a variety of infections caused by bacteria and micro-organisms
    - a medicine for the treatment of patients with COPD.

110. In October, the EAG provided written comments on:

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[34] an inherited condition that causes high levels of LDL (low density lipoprotein) cholesterol
[35] the time period describing the duration of a patient's surgical procedure
[36] a respiratory condition that is usually triggered by an acute viral infection of the upper airway
[37] an incretin derived from the transcription product of the proglucagon gene used in the treatment of diabetes

- medicines used in the treatment of hypertension, diabetic nephropathy[38] and congestive heart failure
- a medicine for the treatment of patients with chronic spontaneous urticaria[39]
- the balance of risks and benefits of Angiotensin Receptor Blockers (ARBs)[40].

111. In November, the EAG discussed, via teleconference, and made recommendations on a medicine for the treatment of asthma in children and adults.

**Chemistry, Pharmacy and Standards Expert Advisory Group (CPSEAG)**

112. The CPSEAG met 11 times and considered and advised on applications for new drugs, abridged applications, variations and pre-hearings. The EAG also provided advice by written correspondence on 10 occasions.

113. In January, the EAG considered and made recommendations on the following:

- a medicine for the treatment of short term and long term conjunctivitis[41]
- a medicine for the treatment of schizophrenia
- a medicine for the treatment of major depressive episodes in adults
- a medicine for the prevention of babies being born with neural tube defects such as Spina Bifida[42]
- a medicine for the treatment of vulvovaginal conditions
- a medicine for the prevention of pregnancy
- a medicine for use as an X-ray contrast media.

114. In February, the EAG considered and made recommendations on the following:

- a product for diagnostic use with an imaging agent
- a radiopharmaceutical[43] product for diagnostic use[44]
- a medicine for the treatment of cancer of the ovary
- a medicine for the treatment of patients with cystic fibrosis to treat lung infections caused by Pseudomonas aeruginosa[45]
- a medicine to make breathing easier for adult patients who have breathing difficulties due to a lung disease called chronic obstructive pulmonary disease (COPD)[46]
- a medicine to help start the birth process
- a nicotine inhalation device for use as a smoking replacement product
- a medicine for the treatment of high blood pressure, heart failure and kidney disease

[38] kidney damage due to diabetes
[39] commonly known as hives, a kind of skin rash notable for pale red, raised, itchy bumps
[40] medicines for the regulation of blood pressure and balance of salt and water
[41] the redness and inflammation of the thin layer of tissue that covers the eye
[42] a series of birth defects that affect the development of the spine and central nervous system
[43] a medicinal product that contains radioactive atoms
[44] a diagnostic radiopharmaceutical is a product which, when injected, temporarily collects in a particular part of the body (for example, a tumour)
[45] a bacterium that frequently infects the lungs of cystic fibrosis patients
[46] the name for a collection of lung diseases including chronic bronchitis, emphysema and chronic obstructive airways disease

- a medicine for the treatment of glaucoma[47].

115. In February, the EAG also provided written comments on:

- an endothelin receptor antagonist (ERA)[48] for the long-term treatment of pulmonary arterial hypertension[49]
- the publication, on the MHRA website, on the suspension of the Teva Marketing Authorisation for levothyroxine.

116. In March, the EAG considered and made recommendations on the following:

- a medicine for the treatment of moderate to severe pain
- a medicine for the treatment and prevention of electrolyte deficiency[50]
- a medicine for the treatment of several types of cancer including chronic myeloid leukaemia[51] and Philadelphia chromosome positive acute lymphoblastic leukaemia[52]
- a medicine for the treatment of stable plaque psoriasis vulgaris[53] amenable to topical therapy in adults
- a medicine for the treatment of medullary thyroid cancer[54].

117. In March, the EAG also provided written comments on a medicine for the treatment of Duchenne muscular dystrophy[55] in patients aged 5 years and older.

118. In April, the EAG considered and made recommendations on the following:

- a medicine for the treatment of multiple myeloma[56]
- a radiopharmaceutical product for use in detecting and evaluating of tumour-draining of the lymph nodes[57]
- a radiopharmaceutical product to help identify brain conditions
- a combination product for the treatment of COPD
- a medicine for use in reducing high pressure in the eye which could lead to glaucoma
- a medicine for the prevention and treatment of vitamin D deficiency.

119. In May, the EAG considered and made recommendations on the following:

- a medicine for the control of the level of phosphorus[58] in the blood in patients with renal failure[59]
- a radiopharmaceutical product for conducting brain function tests

[47] various disorders of the eye that can lead to permanent damage of the optic nerve
[48] a drug that blocks the proteins that constrict blood vessels and raise blood pressure
[49] higher than normal blood pressure
[50] minerals in the cells and blood that conduct electrical impulses and messages
[51] a cancer of white blood cells. These white cells usually help the body to fight infection
[52] a form of leukaemia in which certain abnormal white cells (named lymphoblasts) start growing out of control
[53] redness, scaling and thickness of the skin, caused by skin cells being produced too quickly
[54] cancer that forms in the thyroid gland (an organ at the base of the throat that makes hormones that help control heart rate, blood pressure, body temperature, and weight)
[55] a genetic disorder affecting boys and resulting in muscular degeneration
[56] a blood disease affecting the white blood cells that produce antibodies
[57] lymph nodes are organs spread throughout the body. Their function is to filter out the dead bacteria, viruses, and other dead tissue from the body
[58] a mineral the body uses to digest protein and sugars. It also helps the body absorb calcium
[59] a condition in which the kidneys fail to adequately filter waste products from the blood

- a medicine for advanced prostate cancer
- a medicine for the treatment of a variety of inflammatory diseases including severe asthma, rheumatoid arthritis[60], allergic reactions, some skin conditions and some blood disorders
- a medicine for general anaesthesia
- a medicine for the treatment of depression, and for the treatment of bed-wetting by children
- a steroid to reduce inflammation.

120. In May, the EAG also provided written comments on:

- a medicine for the cutaneous[61] treatment of facial erythema of rosacea[62] in adult patients
- a medicine for use, in combination with other anti-retroviral medicinal products, for the treatment of Human Immunodeficiency Virus (HIV) infected adults and adolescents above 12 years of age
- a medicine for the control of serum phosphorus[63] levels in patients with end stage renal failure[64].

121. In June, the EAG considered and made recommendations on the following:

- a medicine for the treatment of asthma and COPD
- a medicine for the treatment of melanoma[65]
- a medicine for the treatment of chronic thromboembolic pulmonary hypertension (CTEPH)[66] and pulmonary arterial hypertension (PAH)[67]
- a medicine for the treatment of haemangioma[68] of infants
- a radiopharmaceutical product for diagnostic use
- a medicine for the treatment of vitamin D deficiency
- a medicine for symptomatic treatment of subacute and chronic inflammatory joint diseases
- a medicine for the treatment of fungal infections.

122. In July, the EAG considered and made recommendations on the following:

- a medicine for the treatment of Multiple Sclerosis (MS)
- a medicine to improve the symptom and underlying causes of vulvovaginal atrophy (VVA)[69]
- a medicine for the treatment of type 2 diabetes mellitus
- a medicine which prevents unwanted blood clots (thrombosis) from forming in the blood vessels
- a medicine for the treatment of age-related macular degeneration[70]

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[60] a systematic inflammatory disease which manifests itself in multiple joints of the body
[61] applied to the skin
[62] redness of the skin
[63] a chemical in the body which promotes bone growth, energy storage, and nerve and muscle production
[64] severe kidney failure
[65] a type of skin cancer
[66] the blood vessels in the lung are blocked or narrowed with blood clots causing high blood pressure in the lung vessels
[67] the blood vessels in the lung are narrowed by constriction
[68] a benign collection of extra blood vessels that have formed a lump in or under the skin. It can be superficial or deep, and is sometimes called a “strawberry mark” because of its surface appearance
[69] vaginal dryness or itching, which can lead to sore or painful sexual intercourse

- a medicine for the treatment of opoid dependence
- a medicine for the treatment of severe croup[71] in patients aged 6 months to 14 years
- a medicine for the treatment of dehydration.

The EAG was also given a presentation on the conclusions and final outcomes of the review of Teicoplanin under Article 5(3) of Regulation (EC) No 726/2004.

123. In July, the EAG also provided written comments on a medicine for the treatment of cardiovascular disease.

124. In August, the EAG provided written comments on a maintenance bronchodilator treatment to relieve symptoms in adult patients with COPD.

125. In September, the EAG considered and advised on the following:

- a medicine for the treatment of hepatitis C virus infection (HCV infection)[72] in adults
- a medicine for the treatment, as a combination, of chronic HCV infection
- an antiseptic solution for use as a wound and mucosal antiseptic
- a medicine to control the body's immune response, to enable acceptance of transplanted organs
- two medicines for the short-term treatment of mild to moderate bacterial skin infections
- a combination of two medicines for the relief of pain and inflammation, and the reduction of acid produced by the stomach
- a combination of medicines for the reduction of undesired contractions of the bladder, to increase the amount of urine the bladder can hold, to enable urine to pass more readily through the bladder, and facilitate urination
- a medicine for the treatment of open angle glaucoma and ocular hypertension in adults.

126. In October, the EAG considered and advised on the following:

- a medicine for the treatment of Multiple Sclerosis (MS)
- a medicine for the treatment of acne and blackheads
- a medicine to correct the loss of sodium chloride in the body
- Cosopt, an eye drop used for lowering pressure in the eye.

127. In November, the EAG considered and advised on:

- an eye drop indicated for the treatment of glaucoma
- a medicine used for the prevention and treatment of different fungal infections
- a medicine indicated for reducing urine production
- two medicines indicated as combined oral contraceptives

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[70] a disease that damages the part of the eye, known as the macula, which normally enables sharp vision

[71] a respiratory condition that is usually triggered by an acute viral infection of the upper airway. The infection leads to swelling inside the throat

[72] a virus carried by the blood that predominantly affects the liver. It can cause inflammation, scarring and, sometimes, significant liver damage

- a medicine indicated for reducing the levels of testosterone and oestrogen circulating in the body
- a medicine indicated for improving blood circulation in the legs
- two medicines indicated for vitamin D deficiency
- Cosopt, an eye drop used for the treatment of increased pressure in the eye.

128. In November, the EAG also provided written comments on a radiopharmaceutical product for diagnostic use.

129. In December, the EAG considered and advised on:

- a medicine indicated for use in combination with another medicine, for the treatment of HIV infection
- a medicine indicated for the treatment of obesity
- a radiopharmaceutical product for use in detecting and evaluating tumour-draining of the lymph nodes
- a medicine indicated for vitamin D deficiency
- a medicine indicated for the treatment of opioid addiction in adults
- a medicine indicated for use in combination with other medicines, for the treatment of multiple myeloma[73].

The EAG was also updated on regulatory actions taken by the MHRA following previous discussion about the safety of the Cosopt container at meetings of Expert Advisory Groups and the Commission on Human Medicines.

130. In December, the EAG also provided written comments on a product for use, after dilution, as an irrigation solution during eye surgery.

**Gastroenterology, Rheumatology, Immunology and Dermatology Expert Advisory Group (GRIDEAG)**

131. The GRIDEAG met on two occasions during 2013 and provided written comments and advice on nine occasions.

132. In February, the EAG convened and made recommendations on:

- a medicine proposed for use in the treatment of active psoriasis[74] in adults
- a medicine proposed for the treatment of childhood arthritis[75] pain.

133. In February, the EAG provided written comments on a medicine for the treatment of moderate to severe rheumatoid arthritis and active psoriatic arthritis in adult patients.

134. In June, the gastroenterologists provided written comments on a medicine to treat the signs and symptoms of moderately to severely active ulcerative colitis[76] and moderately to severely active Crohn's disease[77].

[73] a cancer of the blood affecting the white blood cells that produce antibodies
[74] a skin condition that causes red, flaky, crusty patches of skin covered silvery scales
[75] a condition that causes pain and inflammation within a joint
[76] inflammatory disease of the large bowel
[77] inflammatory disease of the gastrointestinal tract

135. In September, the EAG provided written comments on a guideline on medicinal products for the treatment of systemic lupus erythematosus[78].

136. In October, the EAG convened and made recommendations on:

- a medicine proposed for use in the treatment of allergic asthma and chronic spontaneous urticaria
- a medicine for the treatment of acne
- a medicine for the treatment psoriatic arthritis.

137. In October, the EAG provided written comments on:

- a paper discussing the increased risk of Varicella-associated serious skin and soft tissue complications following the use of ibuprofen
- a medicine for the treatment of opioid-induced constipation.

138. In November, the EAG provided written comments on:

- a medicine for the treatment of rheumatoid arthritis
- a medicine for the treatment of osteoporosis[79] in men at increased risk of fractures.

139. In December, the EAG provided written comments on:

- a European review of risks and benefits for Protelos (strontium ranelate)
- a European assessment of a safety signal for a medicine to treat psoriatic arthritis.

**Medicines for Women's Health Expert Advisory Group (MWHEAG)**

140. The Medicines for Women's Health (MWH) EAG met on 4 occasions during the year, with 3 face to face meetings and 1 teleconference. Professors Stuart Ralston & Dame Valerie Beral demitted office during the year.

141. The EAG considered the evidence and made recommendations on the following issues with marketed medicines:

- the risk of VTE with use of combined hormonal contraception
- efficacy of levonorgestrel-containing emergency contraception in women with high Body Mass Index
- use of salbutamol for tocolysis
- use of iron-containing IV medicines during pregnancy.

142. Specific members of the EAG considered and made written recommendations on the risks and benefits of strontium ranelate, the risks and benefits of a product for post-menopausal vulval and vaginal atrophy, and the pharmacy availability of ulipristal-containing emergency contraception.

[78] a complex autoimmune disease that can affect multiple organs

[79] a condition that affects the bones, causing them to become weak and fragile and more likely to break

143. The EAG considered and made recommendations on applications for new medicinal products for:

- combined hormonal contraception
- induction of labour
- post-menopausal vulval and vaginal atrophy
- thyroid hormone therapy and/or replacement.

144. Specific members of the EAG considered and made written recommendations on applications for products for prevention of osteoporosis in post-menopausal women.

**Neurology, Pain and Psychiatry Expert Advisory Group (NPPEAG)**

145. The NPPEAG met on one occasion in 2013 and provided written comments and advice on 15 items.

146. In January, the psychiatrists provided written comments for a medicine for the treatment of major depressive episodes in adults.

147. In February, the EAG provided written comments on:

- a medicine proposed for use in the treatment of relapsing remitting Multiple Sclerosis (MS)
- a medicine for the short term treatment of people with sleep disturbances.

The neurologists also provided written comments on:

- a medicine for the treatment of epilepsy
- a medicine for the symptomatic treatment of Pseudobulbar Affect (PBA)[80].

148. In March, the neurologists provided written comments on a medicine for the treatment of Duchenne muscular dystrophy[81].

149. In April, the EAG provided written comments on a radiopharmaceutical product to help identify brain conditions.

150. In April, the neurologists provided written comments on four medicines proposed for the treatment of restless leg syndrome[82].

151. In October, the EAG provided written comments on a medicine for the treatment of Multiple Sclerosis (MS).

152. In October, the pain experts provided written comments on a medicine for the treatment of opioid-induced constipation.

153. In November, the EAG convened and made recommendations on:

[80] a condition characterised by sudden and uncontrollable episodes of crying or laughing
[81] a genetic disorder affecting boys and resulting in muscular degeneration
[82] a common condition affecting the nervous system, which causes an overwhelming, irresistible urge to move the legs

- a medicine to reduce pain
- a medicine to treat opioid drug addiction in adults by acting as a substitute for the addictive drugs.

154. At its meeting in November, the EAG also received updates on:

- the European guidelines on the clinical development of medicinal products intended for the treatment of pain
- the European guideline on the clinical development on medicinal products for the treatment of Autism Spectrum Disorder (ASD)
- the European guideline on the clinical investigation of medicinal products for the treatment of Amyotrophic Lateral Sclerosis[83] (ALS)
- the guideline on clinical investigation of medical products for the treatment of Multiple Sclerosis (MS)
- the concept paper on the need for revision of the guideline on medicinal products for the medicinal products for the treatment of Alzheimer's Disease (AD) and other dementias
- the Diagnostic Statistical Manual of Mental Disorders (DSM-5).

155. In December, the pain experts provided written comments on a medicine to reduce pain.

156. In December, the psychiatrists provided written comments on a medicine for the use in adults to treat obesity and manage weight in conjunction with a low calorie diet and physical exercise.

**Oncology and Haematology Expert Advisory Group (OHEAG)**

157. In 2013, the OHEAG met on one occasion and convened by teleconference on three occasions. The EAG also provided written comments on nine items.

158. In January, the EAG convened by teleconference and made recommendations on:

- a radiopharmaceutical product for diagnostic use
- a medicine for diagnostic use with an imaging agent
- a medicine to treat cancer of the ovary.

159. In February, the haematologists provided comments on a medicine for the treatment of chronic myeloid leukaemia[84] and Philadelphia chromosome positive acute lymphoblastic leukaemia[85].

160. In March, the EAG convened by teleconference and made recommendations on:

- a medicine for the treatment of medullary thyroid cancer[86]
- three medicines for the treatment of prostate cancer
- a medicine proposed for the treatment of giant cell tumour[87] of the bone.

[83] a degenerative disease of the nerve cells that control muscular movement
[84] a blood cancer with too many abnormal white blood cells in the blood forming bone marrow
[85] a leukaemia type with an excess of immature white blood cells in the blood and blood forming bone marrow
[86] a type of cancer that forms in the thyroid gland (an organ at the base of the throat that makes hormones that help control heart rate, blood pressure, body temperature, and weight)

161. In March the EAG provided written comments on a medicine for the treatment of leukaemia.

162. In April the haematologists provided written comments on a medicine for the treatment of multiple myeloma[88].

163. In June the EAG provided written comments on:

- a medicine proposed for use in the treatment of newly diagnosed glioblastoma[89]
- a medicine for the treatment of melanoma.

164. In July, the EAG convened and made recommendations on:

- a medicine for the treatment of pancreatic cancer
- a medicine for the treatment of locally advanced or metastatic breast cancer.

165. In August the EAG provided written comments on a medicine for the treatment of metastatic breast cancer.

166. In October, the EAG provided written comments on:

- a preparative medicine before receiving a bone marrow transplant
- a medicine for the treatment of several types of cancer including chronic myeloid leukaemia[90] and Philadelphia chromosome positive acute lymphoblastic leukaemia[91].

167. In November, the EAG convened by teleconference and:

- made recommendations on a medicine for the treatment of advanced Renal Cell Carcinoma[92]
- were updated on an assessment and action being undertaken in Europe in relation to new data on the risk of serious vascular occlusive events associated with Iclusig (ponatinib)
- were presented with a review of a possible link between etanercept and certain types of brain cancer. This was part of a Europe-wide review of the risk of brain cancer with medicines like etanercept (known as TNF alpha inhibitors). The EAG considered that the data presented in the review did not show a strong link between etanercept and brain cancer. It was noted that the etanercept information that is used by healthcare professionals sufficiently covers the currently-known risk of cancer. However, the EAG agreed that further data on the risk of brain cancers is necessary.

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[87] a tumour of the bone characterised by massive destruction of the end (epiphysis) of a long bone
[88] a disease affecting white blood cells that produce antibodies
[89] a type of malignant brain tumour
[90] a cancer of the white blood cells
[91] a form of leukaemia in which certain abnormal white blood cells (named lymphoblasts) start growing out of control
[92] cancer of the kidney that is advanced or spread to other organs

## Paediatric Medicines Expert Advisory Group (PMEAG)

### Introduction

168. The Paediatric Medicines Expert Advisory Group (PMEAG) advises the Commission on Human Medicines on the safety, quality and efficacy of medicines for paediatric use, including all matters relating to the implementation of the EU Paediatric Regulation. This is the sixth annual report for the PMEAG under its current remit and once again highlights the key role it plays in improving the availability of authorised medicines for children. The report covers the period January to December 2013 during which the EAG met 7 times with 4 meetings being replaced by written procedures.

### Background: Progress with the European Paediatric Regulation

169. The Paediatric Regulation has been in force for seven years. Up to December 2013, the European Medicines Agency (EMA) received 1520 valid PIP applications of which a quarter were for a waiver in all paediatric sub-groups. The European Paediatric Committee (PDCO) has delivered opinions for 69% of these submissions. Overall, 77% of the applications were for new medicinal products, 21% were for extensions to the indication, pharmaceutical form or route of administration and 2% were for off-patent drug substances intended for a paediatric use marketing authorisation (PUMA). Opinions have been given on 665 modifications to PIPs. The rate of application for modifications has increased slightly, the number in 2013 being 15% greater than 2011 compared to a 10% increase in the previous year. Modifications reflect either the further development of the product since the initial PIP or adjustments to development programmes once studies are underway.

170. PDCO has given 53 opinions on whether the studies conducted have complied fully with a PIP. About 32 products have been approved at national or European level with supporting data arising from completed PIPs and others have been updated with information from partially completed PIPs. Paediatric studies in PIPs have led to a number of new paediatric indications or information on studies included in summaries of product characteristics. New dosage forms suitable for use in younger age-groups have been approved in several cases. Up to the end of 2013 15 products have been granted the reward of a 6 month extension in patent protection for conducting paediatric studies. The PM EAG regularly reviews the impact of the Regulation and receives feedback from PDCO to inform its own decision-making. The UK was joint lead Rapporteur/Peer reviewer for the assessment of PIPs in 2013.

171. The UK has continued to play a significant role in the assessment both of older paediatric studies (Article 45) and newer studies as they are completed (Article 46): it has acted as Rapporteur for about a quarter of these European work-sharing procedures (up from a fifth in 2012). Up to the end of December 2013, 161 assessment reports had been published for Article 45 procedures (an increase of 56% on the previous year) and 74 for Article 46. They have led to new paediatric indications for 20 products, additional study information in 22 cases and in 15 instances further safety information has been included in the SmPC. Licences for all products (brand-leader and generic) in the UK containing the active substances continue to be updated on a regular basis to reflect this new information on paediatric use.

172. PMEAG continues to advise on Marketing Authorisation applications and other regulatory submissions accompanied by paediatric data, including safety reviews, in addition to its work to support the Paediatric Regulation.

**Review of the PMEAG contribution in 2013**

**Paediatric Investigation Plans**

173. PMEAG and its individual members advise on PIPs where UK is Rapporteur or Peer Reviewer. There was an 11% increase in the number of PIP applications submitted to the EMA in 2013 compared to 2012. UK delegates have acted as Rapporteur or Peer Reviewer for 15% of PIP submissions, reflecting an increase from previous years (10% in 2012).

174. The PMEAG has discussed 13 PIPs where the UK is Rapporteur and 10 where UK has acted as Peer Reviewer, double the total number discussed in 2012. The advice given covered a range of therapeutic areas. The EAG also provided comments for a PIP for which the UK was volunteer reviewer and which concerned the development of a drug for paediatric cancer patients. Members have also commented in writing on a number of procedures for which the deadlines fell between EAG meetings. The UK continues to make a strong contribution to decisions on the development of paediatric medicines at European level through the provision of delegates and UK experts, including PMEAG members, to the PDCO, its working-groups and ad hoc groups.

**Advice on work-sharing procedures**

175. The EAG considered 7 papers where the UK was Rapporteur for products being assessed under work-sharing procedures which included studies completed before the Regulation came into force.

**Advice related to marketing authorisation applications supported by paediatric data**

176. The EAG reviewed 8 new products and 2 applications to add or extend paediatric use to an existing product. The products covered a range of indications including schizophrenia, treatment of infantile haemangioma, analgesia, treatment of severe breathing problems, prevention or treatment of folic acid deficiency, prevention or treatment of vitamin D deficiency and rickets, prevention or treatment of electrolyte disorders and the management of skin disorders in newborns.

**Safe use of medicines in children**

177. The EAG advised on the paediatric use of the anti-emetic drug, metoclopramide, which was the subject of a European referral procedure. In addition, it reviewed the use of codeine in paediatric analgesia which was also the subject of a European referral procedure under the new Pharmacovigilance Legislation. The EAG also considered the use of chlorhexidine for skin disinfection prior to central venous catheterisation in premature infants. The EAG also assessed the risk of severe skin and soft tissue infection following the use of ibuprofen in children with chicken pox, and advised on the supply of asthma inhalers to schools for emergency use and the development of appropriate protocols for their safe and effective use.

**Other advice related to the use of medicines in the paediatric population**

178. ***Regulatory guidance***: The EAG considered a new European guideline on Paediatric Pharmaceutical Development which sets out the requirements and recommendations for age appropriate and safe paediatric formulations. It also advised on the update of the Paediatric Yellow Card reporting guideline.

179. ***Discontinuations:*** In 2013, the EAG members gave advice on the discontinuation of two medicines for children.

180. Members also raised concerns regarding the inappropriate advertising in a scientific publication of an agent intended for the treatment of bladder disorders.

181. The EAG advised on an application for a paediatric clinical trial protocol and the appropriate dosing schedule of a monoclonal antibody in paediatric patients with a life threatening blood disease.

**Conclusion**

182. During 2013, the Paediatric Medicines EAG again provided invaluable advice which supported the aim of the Paediatric Regulation to improve the number of medicines properly researched and authorised for use in children. It continued to advise on PIPs, their modifications and, increasingly, on the subsequent marketing authorisation applications to extend paediatric use based on the studies in these plans. It also advised on updates to product information as a consequence of studies submitted through European work-sharing procedures. The EAG has continued to provide views across a wide range of therapeutic areas and issues such as discontinuation of paediatric medicines and the development of appropriate regulatory guidance. The EAG continues to participate in reviews of the safe use of medicines in children. This is increasing as a consequence of the new pharmacovigilance legislation.

**Patient and Public Engagement Expert Advisory Group (PPEEAG)**

183. The membership of the Patient and Public Engagement (PPE) EAG was appointed in 2012 following agreement of the terms of reference by the Commission in 2011. Members are primarily lay people, although a small number have a health professional background. The EAG is supported by two lay members from the Commission. The EAG met on four occasions during the year.

184. The EAG developed a work plan to be undertaken over the following 18 months. The topics to be considered covered three discrete areas of work:

- Information improvement
- Internal influence
- External influence.

185. The work plan was endorsed by the Commission.

186. The EAG advised on the importance of medicines information in the digital age. As part of the external influence work-stream they considered and advised on how medicines information could be optimised in the context of the further work being undertaken by the Department of Health in extending the NHS Choices

portal. They also advised on the development of a patient-centred focus to the reporting of adverse drug reactions through the MHRA's Yellow Card portal.

187. As part of the information improvement work-stream the EAG reviewed the recent research findings from the PhD studentship being jointly funded by MHRA and the University of Leeds. This research will provide an evidence base to support the earlier work of the EAG in advising on the UK response to the European Commission's work on the current quality of medicines information.

188. As part of a new drug-driving offence there is a need to provide information to patients and healthcare professionals on those medicines which could impair a patient's ability to drive. The EAG heard from the Department for Transport regarding the new legislation as part of their external influence work-steam. The EAG advised on new medicines information which will support both healthcare professionals and patients in making informed decisions about medicine prescribing and medicine taking.

189. The EAG also began an on-going piece of work on patient involvement in the regulatory decision-making process as part of their internal influence work-stream. To progress this work a task-and-finish group was formed to consider the different models for engagement with patients and the public which might be applicable to the work of the CHM and the assessment staff of the MHRA. The EAG heard from the chair of INVOLVE and National Director for Public Participation and Engagement in Research, the Associate Director of the Patient and Public Involvement Programme at NICE and the Patient Involvement Lead for the National Research Authority. Written materials from a number of other public sector bodies were also considered. The group is preparing an interim report for consideration by the CHM in the next year before finalising its advice in this area.

**Pharmacovigilance Expert Advisory Group (PEAG)**

190. The Commission's Pharmacovigilance EAG membership includes expertise in pharmacovigilance, clinical pharmacology, toxicology, epidemiology, general practice, nursing, pharmacy and also includes lay representation.

191. The EAG met on 10 occasions during 2013 and provided advice by written procedure on a further two occasions (January 2013 and December 2013).

192. The EAG considered papers on the following drug safety issues:

- Intravenous iron-containing medicinal products and hypersensitivity reactions
- Metoclopramide and neurological adverse reactions
- Cardiovascular thrombotic risks of diclofenac
- Risk management of oral diclofenac as a 'Pharmacy' medicine
- Codeine in paediatric analgesia and risk of morphine toxicity
- Methysergide and risk of fibrosis
- Cardiovascular events with clarithromycin and azithromycin
- Drug-drug interaction between proton pump inhibitors and methotrexate
- Aspirin and macular degeneration
- Interferon beta and thrombotic microangiopathy

- Vascular and upper gastrointestinal effects of non-steroidal anti-inflammatory drugs (NSAIDs)
- Allopurinol and Severe Cutaneous Adverse Reactions (SCAR) in patients with renal impairment: association with HLA-B*5801 allele
- The role of paracetamol in the management of osteoarthritis
- GLP (Glucagon-like peptide-1)-based therapies and risk of pancreatitis and pancreatic cancer
- Sodium valproate: use in pregnancy and risk of neurodevelopmental delay and autistic spectrum disorder
- Cosopt (dorzolomide hydrochloride/timolol maleate) preservative-free eye drops and eye injury
- Increased risk of myopathy and rhabdomyolysis with high-dose simvastatin
- Association between cardiovascular events and sodium-containing effervescent, dispersible and soluble drugs.

193. Where major regulatory action or restrictions on use were proposed, advice was also sought from the Commission on Human Medicines. The EAG's advice on many of these issues was subsequently taken forward for further discussion within the European medicines regulatory system.

194. The EAG gave advice on 35 Risk Management Plans and considered the monthly Yellow Card reporting statistics. The EAG considered and advised on MHRA strategies for strengthening vaccine pharmacovigilance and risk management for the national immunisation programme for 2013/2014 and for clarifying the Yellow Card reporting guidelines for adverse drug reactions in children.

195. The EAG considered papers which measured the impact of regulatory action taken previously for dosulepin and piroxicam and provided advice on best practice for designing and reporting future outcome studies.

196. Summary reports based on the minutes of each meeting are published on the MHRA website. The safety advice given by the EAG on the majority of the issues listed above was communicated to healthcare professionals in the UK via the MHRA monthly bulletin, Drug Safety Update.

**Dianette Working Group**

197. In March 2013, the Agency convened an Ad Hoc Group to consider a review, initiated in Europe by the French competent authority, Agence Nationale de Sécurité du Médicament et des produits de santé (ASNM), following their decision in February to suspend Diane 35 and its generics in France within 3 months. The French decision followed a review by ASNM of reports of venous and arterial thromboembolism since the authorisation of Diane 35.

198. The Ad Hoc Group met in April 2013 to review the Risk/Benefit balance. It then provided recommendations to CHM on guidance to be taken into account when considering whether a drug should be prescribed/dispensed by brand name, and how such a requirement should be communicated to prescribers, healthcare professionals and patients.

**Insulins Working Group in Type 2 Diabetes and Risk of Adverse Outcomes**

199. In 2012 an ad hoc expert working group of the CHM was established to consider emerging evidence raising concerns about an increased risk of cancer, adverse cardiovascular outcomes and death in patients with type 2 diabetes treated with exogenous human insulin and insulin analogues. All of the risks in question have long been recognised in association with type 2 diabetes itself, making any causal relationship with insulin treatment difficult to confirm or refute. The expert group evaluated the strength of the evidence for these adverse outcomes with insulin, the need for regulatory action, and how better data may be gathered. The conclusions were presented to the Commission in November 2013. The Commission considered that in general, the results from clinical trials did not support a causal association between insulin use and cancer or adverse cardiovascular outcomes. For both cancer and cardiovascular outcomes, interpretation of results from observational studies was made difficult by limitations in the study methods used. On this basis, the Commission advised that no regulatory action was needed and suggested areas for further work, particularly with respect to the cancer signal.

**National Emergency Stockpile Quality Panel**

200. The National Emergency Stockpile Panel which was formed in April 2010 continues to provide advice to the Emergency Preparedness Group of the Department of Health within the context of its UK Medicines Strategic Stockpile Expiry Contingency Protocol.

201. The Panel did not meet in 2013 but did provide written comments on two occasions, which is consistent with expectations. In future it is expected that the Panel will meet about 1-2 times per year.

**Nicotine Containing Products Working Group**

202. The Nicotine Containing Products Working Group (NCP WG) met once in January 2013 and advised on the research that had been conducted since the last meeting of the NCP WG in May 2011, based on its Terms of Reference.

203. The WG advised on the MHRA's assessment of all available data on:

- A MA application for a NCP
- MHRA funded researched on electronic cigarettes
- Quality, safety and efficacy of unlicensed NCPs
- Current use of electronic cigarettes
- Potential impact of bringing NCPs into medicines regulation
- The draft Tobacco Products Directive and nicotine levels.

204. The WG advised that the regulation of NCPs within the existing medicines regulatory framework was a proportionate way to deliver the benefits of a harm reduction approach and to manage the risks of poor quality and ineffective products. Unlicensed NCPs on the market did not meet appropriate standards of safety, quality and efficacy. Testing data confirmed that nicotine levels varied considerably from the labelled content and the amount of nicotine per product could differ from batch to batch. In terms of how well unlicensed NCPs worked,

there was widely differing amounts of nicotine from the same format with one form delivering what could be an effective therapeutic dose, another a 'placebo' dose. With regards to safety, toxic elements may be included at unexpectedly high doses which could produce adverse effects, particularly in vulnerable patient groups. The Commission subsequently endorsed the conclusions of the NCP WG.

### Review of Non-Prescription Analgesics Working Group

205. In 2013 an ad hoc Working Group was set up by the CHM in the light of evidence about the cardiovascular risks associated with diclofenac and ibuprofen, and following consideration by NICE of the risks and benefits of paracetamol and its role in the management of osteoarthritis. Diclofenac, ibuprofen and paracetamol are all available without prescription under certain circumstances.

206. Considering these separate reviews on the safety of individual analgesics, CHM advised that any further action to minimise the risk of specific OTC analgesics should be taken only after taking into account the safety of other analgesics available without prescription. The ad hoc working group was therefore set up to undertake a review of non-prescription analgesics in general with full and careful consideration of all relevant aspects of the management of pain in the OTC setting.

207. The ad hoc group's membership included expertise in pharmacovigilance, clinical pharmacology, toxicology, epidemiology, general practice, nursing, pharmacy and also includes lay representation.

208. The ad hoc group met on 2 occasions in 2013 – in September and November to agree the terms of reference and consider papers on the following issues:

- An overview of non-prescription oral analgesics authorised in the UK
- Outcome of the consultation exercise MLX 382 on availability of diclofenac as a Pharmacy medicine.

209. The ad hoc group will continue its work considering a paper reviewing the safety of paracetamol, and papers reviewing the cardiovascular risk of ibuprofen, and of naproxen. The ad hoc group is expected to advise the CHM of its conclusions in 2014.

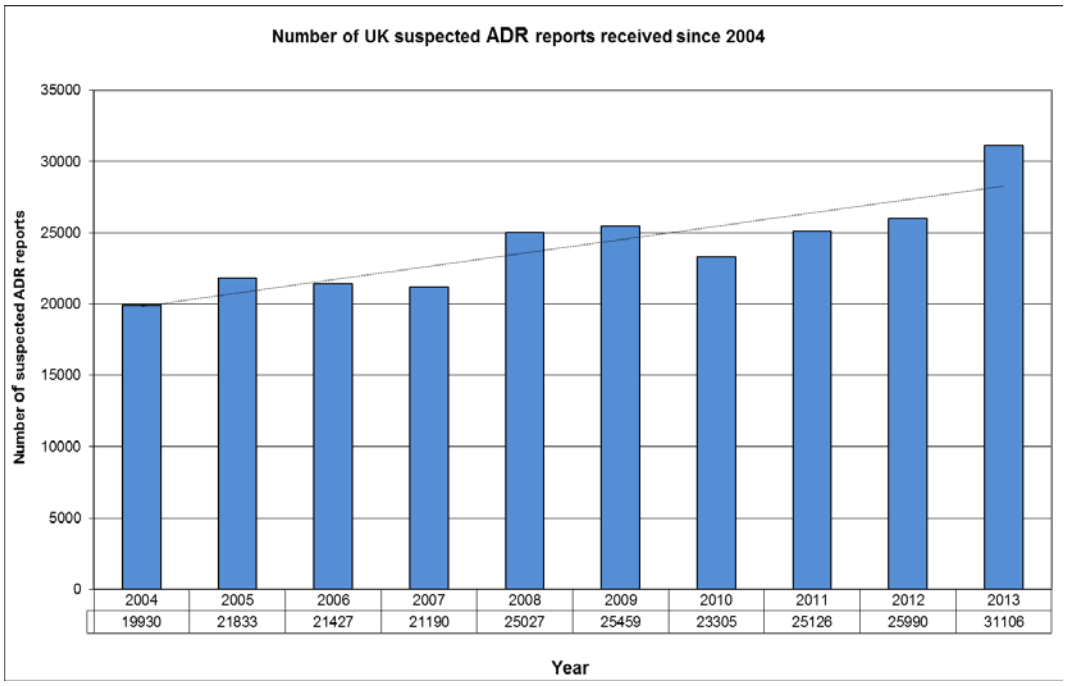
## REPORTING OF SUSPECTED ADVERSE DRUG REACTIONS

210. Suspected Adverse Drug Reactions (ADRs) to medicinal products and vaccines are reported to the CHM and the Medicines and Healthcare products Regulatory Agency (MHRA) on a voluntary basis by healthcare professionals, coroners and, as of January 2005 by patients through the Yellow Card Scheme. Reports are also submitted as a legal requirement by pharmaceutical companies holding marketing authorisations. Information collected through the Yellow Card Scheme is an important means of monitoring drug safety in clinical practice, acting as an early warning system for the identification of previously unrecognised adverse reactions and increasing knowledge of known ADRs.

211. The total number of UK spontaneous suspected ADR reports increased by 20% in 2013 when compared to the previous year, the largest increase seen in the last 10 years. The overall proportion of serious reports remained high at 86%.

212. Figure 1 shows the total number of UK spontaneous Yellow Card reports received from pharmaceutical companies, healthcare professionals and patients in the period 1 January 2004 to 31 December 2013.

**Figure 1 – Graph showing the number of UK spontaneous suspected Adverse Drug Reaction reports from 2004 to 2013**

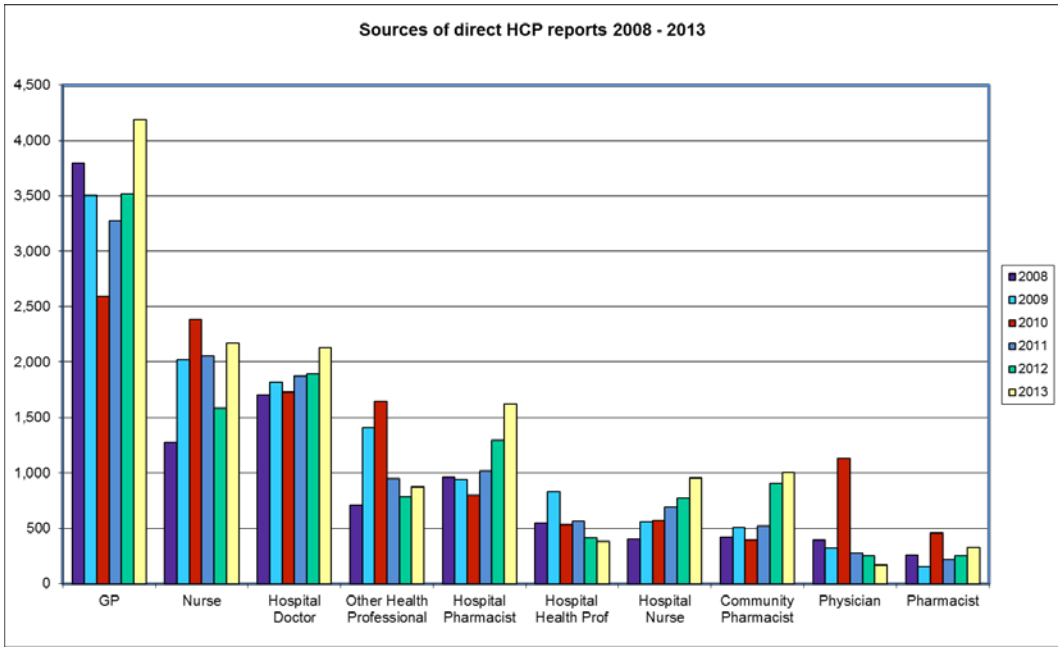



213. Of the total number of UK spontaneous suspected ADR report received in 2013, 46% of reports were received via Industry, 45% directly from healthcare professionals, and 9% from patients, parents and carers.

214. Overall, the annual number of UK spontaneous ADR reports received since 2004 shows an increasing average trend as depicted by the line on the graph in figure 1. The number of suspected ADR reports in 2013 has increased by 56% in 2013 (11,176 reports), when compared to 2004.

215. Direct healthcare professional reports made up 45% of all suspected reports received via the Yellow Card Scheme in 2013. A breakdown of reports by reporter qualification between 2008 and 2013 is shown in Figure 2. To reverse the declining trend in the number of Yellow Card reports received directly from GPs, a focus of the Yellow Card strategy is to improve access to and ease of reporting by this reporter group. In 2013, numbers of GP reports increased by 674 reports (19%) taking GP reporting to its highest level during this time period. In total, GPs accounted for 29% (4,190 reports) of all direct Yellow Cards received by the MHRA in 2013.

**Figure 2 – number of direct ADR reports from 2008 to 2013 by reporter qualification**




*Other health professionals include: dentists, optometrists, coroners, healthcare assistants, paramedics, chiropodists and other non-specified health professionals

216. In 2013, reports from nurses contributed to the second largest proportion of Yellow Cards due to a significant change in the national immunisation programme, with the introduction of four major new programmes based on the advice and recommendations of Joint Committee on Vaccination and Immunisation (JCVI). The new immunisation campaigns include the intranasal influenza vaccine Fluenz in children aged 2-16 years, which began in autumn 2013 with a phased approach in 2-3 year olds with a few regional pilots in primary school children, the rotavirus vaccine Rotarix in infants at 2 and 3 months of age, the shingles vaccine Zostavax in all 70 year olds (as well as an annual phased catch up in 79 year olds), and a new adolescent booster of meningococcal group C conjugate vaccine. The MHRA has been closely monitoring the safety of these immunisation programs and no new safety concerns have been identified to date.

217. In December 2013 a new interactive e-learning unit on ADRs and the Yellow Card Scheme was launched in collaboration with Nursing Times[93]. Free to all nurses who register with the Nursing Times Learning website, completing the unit counts for 2 hours of continuous professional development (CPD) credits. The learning unit is designed to support nurses' understanding of the importance of continuous reporting and monitoring of ADRs which contributes to the safer use of medicines, recognising which type of situations may trigger a report through the Yellow Card Scheme, and to be able to fill out a Yellow Card correctly. The e-learning unit also includes information on where to find up-to-date information on ADRs and how to be able to use that information for patient safety. This e-learning module complements other existing MHRA e-learning modules, such as the BMJ e-learning module and CPPE module for pharmacists which are already available for healthcare professionals on pharmacovigilance and the Yellow Card Scheme.

[93] http://www.mhra.gov.uk/NewsCentre/CON350693

218. The New Medicine Service (NMS), launched in October 2011 is the fourth Advanced Service to be added to the NHS community pharmacy contract in England, and the service has been extended to run until 31 March 2014. It aims to provide early support to patients with long-term conditions to improve patient adherence and to maximise the benefits of newly initiated medicines. Successful implementation of the NMS is envisaged by the Pharmaceutical Services Negotiating Committee (PSNC) and NHS Employers to include an increase in the reporting of Yellow Cards; thereby supporting improved pharmacovigilance, and detection of new safety signals by the MHRA.

219. In addition to this, a public health campaign was launched in February 2013 to highlight the need for GPs, community pharmacists and the public to report suspected ADRs to medicines through the Yellow Card Scheme[94]. The communications campaign was supported by the National Pharmacy Association, the Royal Pharmaceutical Society, five regional Yellow Card Centers, the Company Chemists Association, the Association of Independent Pharmacies and the Royal College of General Practitioners. Key activities to raise awareness of the Scheme included general press and media coverage, distribution of healthcare professional and patient Yellow Card forms to pharmacies, development of case studies showing the value and importance of reporting by doctors, training materials for pharmacists, the use of social media to raise awareness with the public, and the production of a video about Yellow Card reporting and the display of a promotional video for patients in 339 pharmacies across the UK.

220. The introduction of Yellow Card reporting as a quality indicator for successful implementation of the NMS for community pharmacists and the recent communications campaign have contributed to a 75% (390 reports) increase of Yellow Card reports submitted by community pharmacists in 2012 and a further increase of 11% (101) in 2013, with community pharmacy now accounting for 7% (1007) of all direct healthcare professional reports.

221. An important aspect of the Yellow Card communications campaign included targeted messages to healthcare professionals to highlight and raise awareness of the Yellow Card Scheme with patients (including parents and carers) to inform them that they are also able to report suspected side effects directly to the MHRA by completing a Yellow Card. Patient reporting is now an established part of the Scheme, and in 2013 numbers of reports from patients increased by 55% (1,003 reports), accounting for 9% (2,832 reports) of all reports received directly to the Yellow Card Scheme, the highest level of reporting seen in this group in the last five years.

**Signal detection**

222. Signals of new and changing drug safety hazards are detected in a timely manner by the MHRA. Changes in the frequency of ADRs already known to be associated with drugs are also closely monitored through the signal detection process. The drug-event combinations from Yellow Card reports are assessed to identify potential safety signals. In 2013 there were a total of 73 validated signals; these were signals which have been identified by a statistical algorithm which subsequently required additional detailed investigation and review. These signals resulted in direct regulatory action such as updates to product information, whilst

[94] http://www.mhra.gov.uk/NewsCentre/Pressreleases/CON231524

many more contribute to wider reviews alongside other sources of data. Each signal was prioritised[95] and assigned a time frame in which a national position should be reached. A breakdown of the signals and assigned priorities in 2013 is provided in table.

**Table 1: Number of signals assessed in 2013**

| | **Signal Priority[96]** | | | |
|---|---|---|---|---|
| | **Top** | **Increased** | **Standard** | **Not prioritised** |
| **Number of signals** | 0 | 15 | 57 | 1 |

223. In 2013 ADR reports received from members of the public contributed towards 20 signals being detected, this included 9 signals where a member of the public's report stimulated regulatory action. An example was updating product information for clarithromycin and insulin to indicate that a drug interaction may occur.

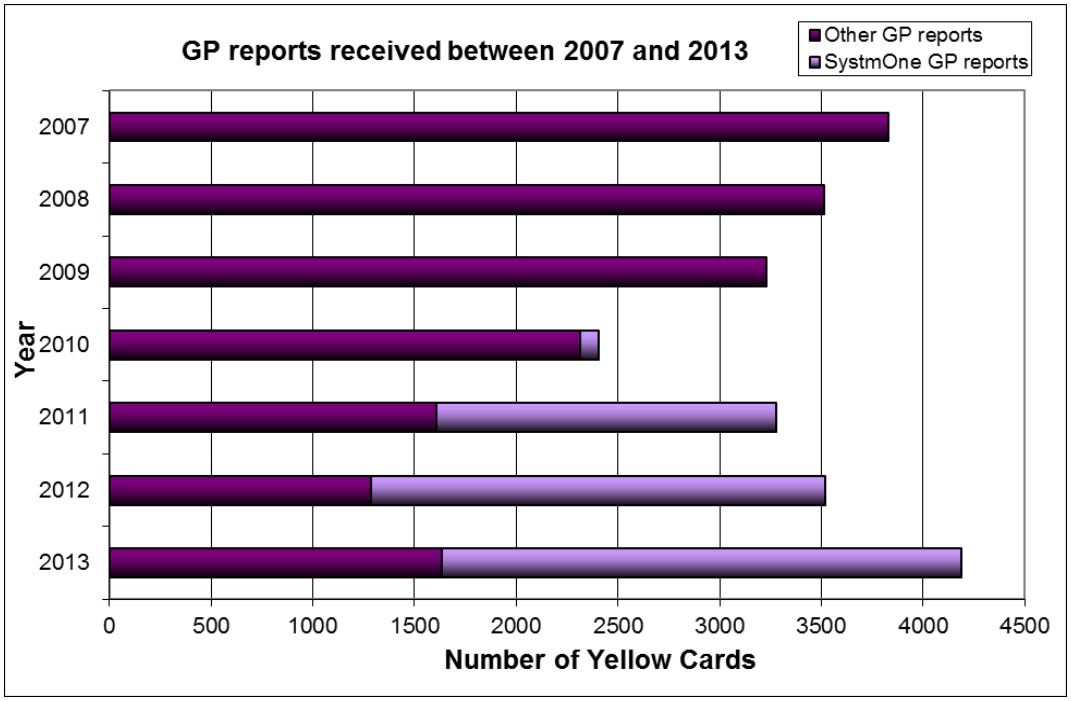
**Electronic reporting**

224. The Yellow Card strategy, which aims to strengthen reporting of ADRs through the Yellow Card Scheme, has a strong focus on facilitating reporting i.e. making reports convenient to access and easy to complete. Easier access to the Yellow Card Scheme can enable the earlier detection of potential drug safety issues, allowing the MHRA to take prompt action to protect public health. As part of this strategy several projects are currently under way to facilitate electronic Yellow Card reporting through integration into clinical IT systems used by healthcare professionals.

225. Since November 2010, GPs have been able to report suspected ADR reports directly using the practice software SystmOne which is used in about 20% of GP practices across the UK. This was the first GP software to include a Yellow Card reporting feature that enables GPs to quickly populate and securely send an electronic Yellow Card to the MHRA directly from their practice software. Figure 3 shows the impact on the number of reports received from GPs since the integration with SystmOne. In 2013, the MHRA received 2,553 electronic GP reports, accounting for 61% of all direct GP reporting. GP reporting accounted for the largest source of direct Yellow Card reports in 2013 at 29% (4190 reports).

[95] Top - action within 3 months, Increased - 6 months, Standard - 12 months, Not prioritised – priority not calculated (created for audit). Please note that these are maximum time frames; many signals will be handled within a shorter timeframe

**Figure 3 – Graph showing the impact on the number of Yellow Card reports received from GPs since the integration with clinical SystmOne software from 2007 to 2013**



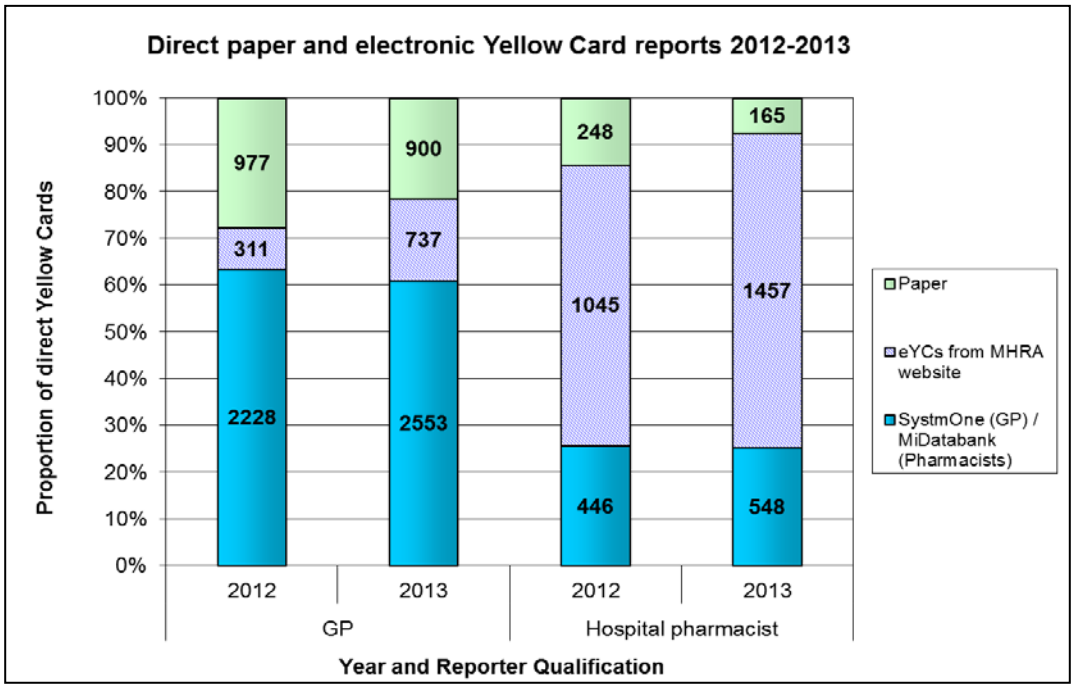

226. The MHRA has developed an NHS information Standard for electronic Yellow Card reporting[96] and implementation of this is currently being pursued through the NHS GP Systems of Choice with the support of the NHS Health and Social Care Information Centre to integrate Yellow Card reporting into GP clinical IT systems.

227. In collaboration with Southampton University Hospitals NHS Trust and the UK Medicines Information (UKMi) service, the MHRA has integrated automated production of Yellow Card reports using their MiDatabank software with medicines information pharmacists at over fifty NHS hospitals in the UK. In 2013, the MHRA received 548 reports through MiDatabank, which accounts for 22% of all electronic pharmacist reports and 17% of all direct pharmacist reports. The continued installation of MiDatabank software including Yellow Card reporting has been supported by a number of activities. In 2012 the MHRA's CEO wrote to NHS Chief Executives encouraging prioritisation of the installation of this software within NHS Trusts, and in 2012 and 2013 workshops and posters on ADR reporting were presented at UKMi conferences. A "league table" of reporting statistics is also regularly provided to UKMi centres.

228. As part of the on-going wider Yellow Card Strategy, work is ongoing to increase the number of reports received via MiDatabank and SystmOne. Figure 4 shows the impact on the number of reports in 2012 and 2013 received from GPs and Hospital pharmacists following efforts to increase reporting through SystmOne and MiDatabank systems.

[96] NHS Information Standards for electronic Yellow Card reporting:
ISB 1582 Electronic Yellow Card: www.isb.nhs.uk/library/standard/243 and
www.isb.nhs.uk/documents/isb-1582

**Figure 4 – Graph showing the breakdown of reporting methods (paper vs. electronic) received directly from GP and Hospital pharmacists between 2012 and 2013**




229. Towards the end of 2012 a third system for direct ADR reporting from a secondary care setting was also established as a result of collaboration between MHRA, Newcastle upon Tyne NHS Foundation Trust and Cerner, a supplier of healthcare information technology. This new collaboration has allowed the development of Cerner's software to include automatic prompts for clinicians to consider reporting an adverse drug reaction to the Yellow Card Scheme when treatment of a medicine is stopped. In 2014 further work will be carried out to roll out this software system functionality across the UK.

230. Electronic reporting is also the most popular way of reporting for members of the public. In 2013 the MHRA received 2,362 suspected ADR reports from patients, parents and carers, over 84% of which were electronically reported.

**Yellow Card website enhancements**

231. In July 2012 following the introduction of the new pharmacovigilance legislation, the Yellow Card website was updated to ask reporters if a side effect was related to a medication error, and again in early October 2013 to prompt reporters to provide important information on the brand name and batch numbers for biological medicines and vaccines. The next stage of Yellow Card website enhancements includes changes to support the reporting on adverse effects of medicines taken during pregnancy and to facilitate better collection of data on suspected ADRs occurring in children associated with medicines being taken by the mother or father.

232. The MHRA has also launched a Yellow Card training site for healthcare professionals, which functions in the same way as the normal online Yellow card website and gives healthcare professionals the opportunity to practice filling in a Yellow Card online.

## Yellow Card Centres

233. The Yellow Card Scheme covers the entire United Kingdom, and to boost reporting in regional areas five Yellow Card Centres (YCCs) operate in the UK (Wales, West Midlands, Scotland, Northern and Yorkshire, North West). The YCCs undertake valuable work relating to the promotion and education of health professionals and patient organisations on ADR reporting through the Yellow Card Scheme, communicating drug safety messages and in academic research.

234. The Commission is grateful for the co-operation of those healthcare professionals and patients who have submitted reports of suspected ADRs and who have supported the reporting of suspected ADRs to the Yellow Card Scheme.

## MEMBERSHIP OF THE COMMISSION ON HUMAN MEDICINES (CHM)

### Chair

**Professor Stuart Ralston**[97] MB ChB MD FRCP FMedSci FRSE
Arthritis Research UK Professor of Rheumatology, University of Edinburgh, Western General Hospital, Edinburgh

### Members

**Professor Deborah Ashby**[98] OBE BSc MSc PhD CStat Hon. MFPHM Hon. MRCR FMedSci
Professor of Medical Statistics and Clinical Trials Co-Director of Imperial Clinical Trials Unit, School of Public Health, Imperial College London

**Mrs Alison Bowser**[99]
Lay Representative. Patient and Public Involvement Officer, Research Design Service, Southampton University & National Institute for Health Research

**Professor Derek H Calam**[100] OBE MA DPhil Hon DSc CChem FRSC FRSA Hon MRPharmS Hon MTOPRA
Visiting Professor of Pharmaceutical Sciences at the University of Strathclyde

**Professor Janet H Darbyshire**[101] CBE MB ChB FMedSci FRCP FFPH FRSS (Hon)
Emeritus Professor of Epidemiology, University College London

**Dr J Colin Forfar**[102] BSc (Hons) MBChB PhD MD MA FRCP FRCP (Edin)
Consultant Physician and Cardiologist, John Radcliffe Hospital, Oxford

**Ms Amanda Hoey**[103]
Lay Representative. Director, Consumer Health Consulting Ltd

**Dr Siraj Misbah** MBBS (Hons) MSc FRCP FRCPath
Consultant Clinical Immunologist, Lead for Clinical Immunology, Oxford University Hospitals

**Professor David G C Owens**[104] MD FRCP FRCPsych
Professor of Clinical Psychiatry, Edinburgh University

**Professor B Kevin Park** BSc PhD FMedSci FRCP (Hon) FBTS
Director of MRC Centre for Drug Safety Science, Professor of Pharmacology & Head of Institute of Translational Medicine, University of Liverpool

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[97] Appointed as Chair 12 February 2013 - 11 February 2017 (Commissioner: 1 June 2010 - 11 February 2013)
[98] Re-appointed 1 January 2013 - 31 December 2014
[99] Re-appointed 1 January 2013 - 31 December 2014
[100] Retired 17 October 2013
[101] Re-appointed 1 January 2013 - 31 December 2014
[102] Chair of Cardiovascular, Diabetes, Renal, Respiratory and Allergy Medicines EAG
[103] Re-appointed 1 January 2013 - 31 December 2014
[104] Chair of Neurology, Pain & Psychiatry EAG

**Professor Munir Pirmohamed**[105] MB ChB (Hons) PhD FRCP FRCP (Edin) FMedSci
Professor of Clinical Pharmacology, University of Liverpool, NHS Chair of Pharmacogenetics and Director of the Wolfson Centre for Personalised Medicine

**Carolyn, Lady Roberts** RGN RHV MSc DUniv
Member of The Ethox Foundation – Oxford Centre for Ethics and Communication in Healthcare Practice, Healthcare Visitor

**Professor Rosalind L Smyth**[106] MA MBBS MD FRCPCH FFPM (Hon) FMedSci
Director, UCL Institute of Child Health, London

**Professor Kevin M G Taylor**[107] BPharm PhD MRPharmS
Chair of the British Pharmacopoeia Commission and Professor of Clinical Pharmaceutics, UCL School of Pharmacy, London

**Dr Angela E Thomas**[108] MB BS PhD FRCP FRCPath FRCPCH
Consultant Paediatric Haematologist, Royal Hospital for Sick Children, Edinburgh

**Professor Simon H L Thomas** BSc MBBS MD FRCP FRCP (Edin)
Professor of Clinical Pharmacology and Therapeutics, Newcastle University and Consultant Physician, Newcastle Hospitals NHS Foundation Trust

**Professor Ian V D Weller**[109] BSc MB BS MD FRCP Hon FRCP (Glas) **(Vice Chair)**
Emeritus Professor of Sexually Transmitted Diseases, University College London Medical School

**Invited Experts to Commission meetings:**

**Dr Amanda Adler** BA MD
Consultant Physician, Clinical Lead Diabetes Institute of Metabolic Science Wolfson Diabetes & Endocrine Clinic, Addenbrooke's Hospital, Cambridge University Hospitals (attended September and via teleconference November 2013)

**Dr Terry Aspray** MBBS MD FRCP
Honorary Senior Lecturer, Newcastle University (attended December 2013)

**Dr Barbara A Bannister**[110] MBE MSc FRCP
Consultant in Infectious and Tropical Diseases, Royal Free Hospital, London (attended January, March, April, May, June, July, September, October, November and December 2013)

**Professor Julian Bion** FRCP FRCA FFICM MD
Professor of Intensive Care Medicine, University of Birmingham and Dean of the UK Faculty of Intensive Care Medicine (attended June 2013)

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[105] Chair of Pharmacovigilance EAG
[106] Appointment ended 31 December 2013, Chair of Paediatric Medicines EAG
[107] Chair of Chemistry, Pharmacy and Standards EAG
[108] Chair of Clinical Trials, Biologicals & Vaccines EAG; and Acting Chair of Oncology and Haematology EAG
[109] Re-appointed 1 January 2013 - 31 December 2014
[110] Acting Chair of Anti-Infectives, HIV/AIDS and Hepatology EAG

**Professor Sir Stephen Bloom** FMedSci
Head of Division, Diabetes, Endocrinology and Metabolism, Imperial College London (attended January 2013)

**Professor Mark D Bower**[111] MA MB BChir PhD FRCP FRCPath
Consultant Medical Oncologist, Chelsea & Westminster Hospital, London (attended March 2013)

**Dr Christopher Derry** MD FRCP
Consultant Neurologist, Western General Hospital, Edinburgh (attended March 2013)

**Dr Iolo Doull**[112] MRCP DM FRCPCH
Consultant Respiratory Paediatrician, Respiratory/Cystic Fibrosis Unit, Children's Hospital for Wales, Cardiff (via teleconference September 2013)

**Dr Ailsa Gebbie**[113] MB ChB FRCOG FRCPE FFSRH
Consultant Gynaecologist and Deputy Director, Chalmers Centre, Edinburgh (attended May 2013)

**Dr Richard Hobson**[114] MB BS MRCP (UK) FRCPath PhD
Consultant Microbiologist and Honorary Senior Lecturer, Leeds Teaching Hospitals (attended September 2013)

**Mr Anthony King**[115] MD MMedSci FRCOphth
Consultant Ophthalmologist, Department of Ophthalmology, Queens Medical Centre, Nottingham (attended November 2013)

**Dr Rebecca Mann**[116] BMBS FRCPCH
Consultant Paediatrician, Taunton and Somerset NHS Foundation Trust (attended March, October, November and December 2013)

**Ms Ann McMurray** BSc (dist) Child Health. RGN RSCN
Paediatric Asthma Nurse Specialist (via teleconference September 2013)

**Professor Ann Millar**[117] MBChB MD FRCP
Professor in Respiratory Medicine, Bristol University & Honorary Consultant North Bristol NHS Trust (via teleconference November 2013)

**Dr Hilary Pinnock**[118] MB ChB (Hons) MRCGP MD
Reader and Principal in General Practice, Allergy and Respiratory Research Group, University of Edinburgh (via teleconference September 2013)

**Professor Shirley Price**[119] MSc PhD FBTS ERT FHEA FSB
Associate Dean of Learning and Teaching, Department of Biochemical and

[111] Member of Oncology and Haematology EAG
[112] Member of Cardiovascular, Diabetes, Renal, Respiratory and Allergy Medicines EAG
[113] Chair of Medicines for Women's Health EAG
[114] Member of Anti-Infectives, HIV/AIDS and Hepatology EAG
[115] Member of the Ophthalmic External Expert Panel
[116] Member of Paediatric Medicines EAG
[117] Vice Chair of Cardiovascular, Diabetes, Renal, Respiratory and Allergy Medicines EAG
[118] Member of Cardiovascular, Diabetes, Renal, Respiratory and Allergy Medicines EAG
[119] Member of Paediatric Medicines EAG

Physiological Sciences, Institute of Biosciences and Medicine, Faculty of Health and Medical Sciences, University of Surrey (attended April, May, June, July, September, October, November and December 2013)

**Professor Peter Sandercock**[120] MA DM FRCP (Edin) FMedSci
Professor of Medical Neurology and Honorary Consultant Neurologist, University of Edinburgh (attended September 2013)

**Professor John F Smyth**[121] MD FRCP FRCS FRCR FRSE
Emeritus Professor of Medical Oncology, University of Edinburgh (attended May and July 2013)

**Professor Mike Thomas** MBBS FRCP PhD
Professor of Primary Care Research, University of Southampton and Chief Medical Officer, Asthma UK (via teleconference September 2013)

**Dr Christopher Weir**[122] BSc (Hons) PhD MSc FRRS C.Stat C.Sci
Reader in Medical Statistics, Centre for Population Health Sciences, University of Edinburgh (attended June, September, November and December 2013)

**Professor Faith M Williams** MA PhD FBTS
Professor of Toxicology, Medical Toxicology Centre and Institute of Cellular Medicine, Newcastle University (attended January and March 2013)

**Dr Frances Williams**[123] BSc MBBS MRCP PhD CCST FRCP (Edin)
Reader in Genetic Epidemiology and Hon Consultant Rheumatologist, King's College London (attended June 2013)

**Professor Anthony G Wilson**[124] MB BCH BAO DCH PhD FRCP
Professor of Rheumatology, Medical School, University of Sheffield (attended May 2013)

**Dr Geoffrey Wong**[125] MA MD (Res) MBBS MRCGP FHEA
GP Principal and Senior Lecturer in Primary Care, Queen Mary University of London (attended January, February, March, April, May, June, July, September, November and December 2013)

**Professor Ian Young**
Centre Director, School of Medicine, Dentistry and Biomedical Sciences, Queen's University, Belfast (attended April 2013)

[120] Member of Neurology, Pain & Psychiatry EAG
[121] Member of Oncology and Haematology EAG
[122] Member of Clinical Trials EAG; Member of Clinical Trials, Biologicals & Vaccines EAG; Member of Neurology, Pain & Psychiatry EAG
[123] Member of Gastroenterology, Rheumatology, Immunology & Dermatology EAG
[124] Chair of Gastroenterology, Rheumatology, Immunology & Dermatology EAG
[125] Member of Paediatric Medicines EAG

**Observers of Commission meetings:**

**Ms Hellen Adom**[126] BA MA
Outreach Assistant, NHS Sickle Cell & Thalassaemia Screening Programme, London (attended July 2013)

**Miss Derry Begho**
Campaigns Assistant, Policy and Public Affairs Asthma UK (attended September 2013)

**Dr Stephen McWilliam** BA (Oxon) MBBS MRCPCH
MRC Clinical Pharmacology and Therapeutics Research Fellow, University of Liverpool, Liverpool (attended October 2013)

**Ms Patricia Parris**
Policy Officer, Department of Health (attended September 2013)

**Mrs Bronwen Thompson**
Formerly Asthma Lead for Department of Health Respiratory Team (attended September 2013)

**Dr Lauren Walker** BSc (Hons) MB ChB (Hons) MRCP (UK)
MRC Clinical Pharmacology & Therapeutics Research Fellow, University of Liverpool, Liverpool (attended October 2013)

**Mr Phil Willan**[127] MSc
Lay Representative. Member of the Royal College of Physicians' (RCP) Patient and Carer Network; Member of the RCP Joint Speciality Committee (JSC) for Renal Medicine, Healthcare Associated Infections Working Group, Specialist Advisory Committee for Renal Medicine, JSC for Allergy and Immunology, Faculty of Forensic and Legal Medicine, Federation CPD Policy Committee and Equality and Diversity Monitoring Committee (attended July 2013)

**Dr Vincent Yip** MSc PhD FBTS ERT FHEA
MRC Clinical Fellow in Clinical Pharmacology and Therapeutics, University of Liverpool, Liverpool (attended October 2013)

**The following Department of Health official attended for specific agenda items:**

**Ms Susan Grieve**
Principal Pharmacist, Department of Health (attended March 2013)

[126] Member of Patient and Public Engagement EAG
[127] Member of Cardiovascular, Diabetes, Renal, Respiratory and Allergy Medicines EAG; Member of Patient and Public Engagement EAG; Member of Pharmacovigilance EAG

**The following National Institute for Health and Care Excellence (NICE) officials attended for specific agenda items:**

**Professor Philip Conaghan**
Guideline Development Group Chair

**Ms Susan Latchem**
Operations Director at the National Clinical Guideline Centre

**Ms Vanessa Nunes**
Guideline Lead and Senior Research Fellow at the National Clinical Guideline Centre

**Mr Ben Doak**
Guideline Commissioning Manager, NICE

## MEMBERSHIP OF THE ANTI-INFECTIVES, HIV/AIDS AND HEPATOLOGY EXPERT ADVISORY GROUP

### Remit

To advise the Commission on the safety and efficacy of medicines for use in infections including HIV, AIDS and hepatic diseases.

### Acting Chair

**Dr Barbara A Bannister** MBE MSc FRCP
Consultant in Infectious and Tropical Diseases, Royal Free Hospital, London

### Members

**Dr Sanjay Bhagani** BSc MB ChB FRCP
Consultant Physician in Infectious Diseases/HIV Medicine, Royal Free Hospital, London

**Professor David Dockrell** MB BCh MD FRCPI FRCP (Glas) FACP
Professor of Infectious Diseases, Medical School University of Sheffield

**Dr Richard Hobson**[128] MB BS MRCP (UK) FRCPath PhD
Consultant Microbiologist and Honorary Senior Lecturer, Leeds Teaching Hospitals

**Dr Susan M Hopkins** MB ChB BAO (Hons) BA FRCPI
Consultant in Infectious Diseases and Microbiology, Royal Free Hampstead NHS Trust, Healthcare Epidemiologist, Health Protection Agency, Honorary Senior Lecturer, University College London

**Dr Hermione Lyall** BSc MB ChB MRCP
Consultant in Paediatric Infectious Diseases, St Mary's Hospital, Imperial College Healthcare NHS Trust, London

**Dr Philip N Monk** MB ChB FFPH
Consultant in Health Protection Public Health England, East Midlands Centre, Leicester

**Professor Kevin Moore** BSc MB BS PhD FRCP
Professor of Hepatology, Royal Free Hospital, London

**Professor Deenan Pillay**[129] BSc PhD MB BS FRCPath
Head, Dept of Infection & Professor of Virology, Department of Infection, University
College London

[128] Appointed 18 April 2013 - 17 April 2017
[129] Resigned 6 September 2013

**Professor Robert C Read** MBChB BMedSci MRCP MD FRCP
Professor of Infectious Diseases and Hon. Consultant Physician, University of Southampton and Southampton General Hospital

**Ms Hilary A Shenton** CPFA
Lay Representative. Retired Secretary to the School of Medicine, University of Sheffield

**Mrs Margaret V Shotter**[130] BSc MSc
Lay Member

**Professor Ian V D Weller** BSc MB BS MD FRCP (Hon) FRCP (Glas)
Emeritus Professor of Sexually Transmitted Diseases, University College London Medical School

[130] Appointment ended on 13 January 2013

## MEMBERSHIP OF THE BIOLOGICALS AND VACCINES EXPERT ADVISORY GROUP
**(1 January to 17 April 2013)**

### Remit

To advise the Commission on the quality, safety and efficacy of medicinal products of biological or biotechnological origin including vaccines which are the subject of marketing authorisation applications and to advise on such other matters as are referred to it.

### Chair

**Dr Angela E Thomas** MB BS PhD FRCP FRCPath FRCPCH
Consultant Paediatric Haematologist, Royal Hospital for Sick Children, Edinburgh

### Members

**Professor Derek H Calam**[131] OBE MA DPhil Hon DSc CChem FRSC FRSA Hon MRPharmS Hon MTOPRA
Visiting Professor of Pharmaceutical Sciences at the University of Strathclyde

**Dr Elwyn Griffiths** BSc PhD DSc CChem FRSC
Consultant in Biologicals and Vaccines, World Health Organization; Formerly Director General, Biologics and Genetic Therapies Directorate, Health Canada, Ottawa, Canada

**Professor Sir Andrew Hall**[132] MBBS MSc PhD FMedSci
Professor of Epidemiology, London School of Hygiene and Tropical Medicine & Chairman of the Joint Committee on Vaccination and Immunisation

**Dr Stephen C Inglis**[133] BSc PhD **(Vice Chair)**
Director, National Institute for Biological Standards and Control (NIBSC)

**Dr Helen J Lachmann** MD FRCP
Reader and Honorary Consultant in Amyloidosis and Renal Medicine, University College London

**Professor Christopher Mason** MBBS PhD FRCS FRCSI
Professor of Regenerative Medicine Bioprocessing, University College London

**Professor Elizabeth Miller** OBE BSc MBBS FRCPath FFPHM FMedSci
Consultant Epidemiologist, Immunisation Department, Centre for Infections, Health Protection Agency

**Professor Clive W Mulholland** BSc PhD CSci FIBMS SFHEA FRSA
Deputy Vice Chancellor, University of South Wales – Lay Representative

**Professor Robert C Read** MBChB BMedSci MRCP MD FRCP

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[131] Resigned 18 April 2013
[132] Resigned 31 March 2013
[133] Resigned 31 March 2013

Professor of Infectious Diseases and Hon. Consultant Physician, University of Southampton and Southampton General Hospital

**Dr Peter F Searle** BA PhD
Senior Lecturer, School of Cancer Sciences, University of Birmingham

**Professor Kevin Shakesheff** BSc PhD FRPharmS
Head of School of Pharmacy and Professor of Drug Delivery and Tissue Engineering, University of Nottingham

**Mrs Margaret V Shotter** BSc MSc
Lay Member

**Professor Owen Thomas** BSc PhD AMIChemE
Director of Biochemical Engineering, School of Chemical Engineering, University of Birmingham

**Dr Robin Thorpe**[134] BSc PhD FRCPath
Head, Division of Biotherapeutics, National Institute for Biological Standards and Control (NIBSC)

[134] Resigned 31 March 2013

## MEMBERSHIP OF THE CLINICAL TRIALS EXPERT ADVISORY GROUP
## (1 January to 17 April 2013)

### Remit

To advise the Commission on:

- First Time in Man (FTIM) studies with new compounds acting (directly or indirectly) via the immune system with a novel target or a novel mechanism of action or having a secondary potential effect on the immune system via a mechanism of action which currently is not well characterised
- FTIM studies with novel compounds acting via a possible or likely species specific mechanism
- Any FTIM studies which are otherwise seen as requiring expert advice
- Other clinical trials involving classes of compound where MHRA may wish to seek external expert advice or CHM may wish to have oversight
- Provide expert advice on whether a product's mechanism of action is novel and comes within the scope of the EAG
- Provide MHRA with expert advice on pre-meeting scientific advice documentation for within scope compounds
- Other clinical trials where MHRA may wish to seek advice or where there is a difficult risk benefit balance
- Other clinical trials involving products where a new class safety issue has been identified

### Chair

**Professor Sir Robert Lechler**[135] MB ChB PhD FRCP FRCPath FMedSci
Vice-Principal (Health), King's College London

### Members

**Dr Susan M Bews**[136] BSc MBBS LRCP MRCS PFPM FRCP Lon FRCPE FRCPGlas
Immediate Past President of the Faculty of Pharmaceutical Medicine

**Professor Derek H Calam**[137] OBE MA DPhil Hon DSc CChem FRSC FRSA Hon MRPharmS Hon MTOPRA
Visiting Professor of Pharmaceutical Sciences at the University of Strathclyde

**Professor Mary Collins**[138] BA PhD

[135] Resigned 5 March 2013
[136] Resigned 26 April 2013
[137] Resigned 18 July 2013
[138] Re-appointed 15 February 2013 - 14 February 2017

Professor of Immunology, Dean of the Faculty of Life Sciences, Director of the MRC/UCL Centre for Medical Molecular Virology

**Professor Janet H Darbyshire**[139] CBE MB ChB FMedSci FRCP FFPH FRSS (Hon)
Emeritus Professor of Epidemiology, University College London

**Professor Andrew J T George** MA PhD DSc FRCPath FHEA FRSA FSB
Vice Principal (Education and International), Brunel University, London

**Professor John D Isaacs** BSc (Hon) MB BS PhD FRCP
Director of the Institute of Cellular Medicine & Professor of Clinical Rheumatology, Medical School, Newcastle University

**Professor B Kevin Park** BSc PhD FMedSci FRCP (Hon) FBTS
Director of MRC Centre for Drug Safety Science, Professor of Pharmacology & Head of Institute of Translational Medicine, University of Liverpool

**Professor Munir Pirmohamed**[140] MB ChB (Hons) PhD FRCP FRCP (Edin) FMedSci
Professor of Clinical Pharmacology, University of Liverpool, NHS Chair of Pharmacogenetics and Director of the Wolfson Centre for Personalised Medicine

**Dr Stephen Poole** PhD
Consultant: Biological Medicines and Vaccines

**Mrs Madeleine Wang** BA (Hons)
Lay Member - Patient Advocate

**Dr Christopher Weir** BSc (Hons) PhD MSc FRSS C.Stat C. Sci
Reader in Medical Statistics, Centre for Population Health Sciences, University of Edinburgh

[139] Re-appointed 1 January 2013 - 31 December 2014
[140] Resigned 24 May 2013

## MEMBERSHIP OF THE CLINICAL TRIALS, BIOLOGICALS & VACCINES EXPERT ADVISORY GROUP
## (18th April 2013 onwards)

### Remit

To advise the Commission on:

- First Time in Man (FTIM) studies with new compounds acting (directly or indirectly) via the immune system with a novel target or a novel mechanism of action or having a secondary potential effect on the immune system via a mechanism of action which currently is not well characterised
- FTIM studies with novel compounds acting via a possible or likely species specific mechanism
- Any FTIM studies which are otherwise seen as requiring expert advice
- Other clinical trials involving classes of compound where MHRA may wish to seek external expert advice or CHM may wish to have oversight
- Whether a product's mechanism of action is novel and comes within the scope of the EAG
- Pre-meeting scientific advice documentation for within scope compounds
- Other clinical trials where MHRA may wish to seek advice or where there is a difficult risk benefit balance
- Other clinical trials involving products where a new class safety issue has been identified
- The quality, safety and efficacy of medicinal products of biological or biotechnological origin including vaccines which are the subject of marketing authorisation applications; and to advise on such other matters as are referred to it.

### Chair

**Dr Angela E Thomas**[141] MB BS PhD FRCP FRCPath FRCPCH
Consultant Paediatric Haematologist, Royal Hospital for Sick Children, Edinburgh

### Members

**Professor Derek H Calam**[142] OBE MA DPhil Hon DSc CChem FRSC FRSA Hon MRPharmS Hon MTOPRA
Visiting Professor of Pharmaceutical Sciences at the University of Strathclyde

[141] Appointed as Chair 18 April 2013
[142] Re-appointed 1 November 2013 - 30 October 2014

**Professor Mary Collins**[143] BA PhD
Professor of Immunology, Dean of the Faculty of Life Sciences, Director of the MRC/UCL Centre for Medical Molecular Virology

**Professor Janet H Darbyshire** CBE MB ChB FMedSci FRCP FFPH FRSS (Hon) **(Vice Chair)**
Emeritus Professor of Epidemiology, University College London

**Professor Andrew J T George**[144] MA PhD DSc FRCPath FHEA FRSA FSB
Vice Principal (Education and International), Brunel University, London

**Dr Elwyn Griffiths** BSc PhD DSc CChem FRSC
Consultant in Biologicals and Vaccines, World Health Organization. Formerly Director General, Biologics and Genetic Therapies Directorate, Health Canada, Ottawa, Canada

**Professor John D Isaacs**[145] BSc (Hon) MB BS PhD FRCP
Director of the Institute of Cellular Medicine & Professor of Clinical Rheumatology, Medical School, Newcastle University

**Dr Helen J Lachmann**[146] MD FRCP **(Vice Chair)**
Reader and Honorary Consultant in Amyloidosis and Renal Medicine, University of London

**Professor Christopher Mason** MBBS PhD FRCS FRCSI
Professor of Regenerative Medicine Bioprocessing, University College London

**Professor Elizabeth Miller**[147] OBE BSc MBBS FRCPath FFPHM FMedSci
Consultant Epidemiologist, Immunisation Department, Centre for Infections, Health Protection Agency

**Dr Siraj Misbah**[148] MBBS (Hons) MSc FRCP FRCPath
Consultant Clinical Immunologist, Lead for Clinical Immunology, Oxford University Hospitals

**Professor Clive W Mulholland** BSc PhD CSci FIBMS SFHEA FRSA
Deputy Vice Chancellor, University of South Wales – Lay Representative

**Professor B Kevin Park** BSc PhD FMedSci FRCP (Hon) FBTS
Director of MRC Centre for Drug Safety Science, Professor of Pharmacology & Head of Institute of Translational Medicine, University of Liverpool

**Dr Stephen Poole**[149] PhD
Consultant: Biological Medicines and Vaccines

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[143] Resigned 5 November 2013
[144] Re-appointed 12 November 2013 - 11 November 2017
[145] Appointment ended 11 November 2013
[146] Appointed as Vice Chair from 11 July 2013 (previously a member); Re-appointed 12 November 2013 - 11 November 2017
[147] Re-appointed 17 October 2013 - 16 October 2017
[148] Appointed 18 April 2013 - 30 June 2016
[149] Re-appointed 12 November 2013 - 11 November 2017

**Professor Robert C Read** MBChB BMedSci MRCP MD FRCP
Professor of Infectious Diseases and Hon. Consultant Physician, University of Southampton and Southampton General Hospital

**Dr Peter F Searle** BA PhD
Senior Lecturer, School of Cancer Sciences, University of Birmingham

**Professor Kevin Shakesheff** BSc PhD FRPharmS
Head of School of Pharmacy and Professor of Drug Delivery and Tissue Engineering, University of Nottingham

**Mrs Margaret V Shotter** BSc MSc
Lay Member

**Professor Owen Thomas** BSc PhD AMIChemE
Director of Biochemical Engineering, School of Chemical Engineering, University of Birmingham

**Mrs Madeleine Wang**[150] BA (Hons)
Lay Member - Patient Advocate

**Dr Christopher Weir** BSc (Hons) PhD MSc FRSS C.Stat C. Sci
Reader in Medical Statistics, Centre for Population Health Sciences, University of Edinburgh

[150] Re-appointed 12 November 2013 - 11 November 2017

## MEMBERSHIP OF THE CARDIOVASCULAR, DIABETES, RENAL, RESPIRATORY AND ALLERGY EXPERT ADVISORY GROUP

### Remit

To advise the Commission on the safety and efficacy of medicines for use in cardiovascular, diabetic, renal, respiratory and allergic diseases.

### Chair

**Dr J Colin Forfar** BSc (Hons) MBChB PhD MD MA FRCP FRCP (Edin)
Consultant Physician and Cardiologist, John Radcliffe Hospital, Oxford

### Members

**Professor Houman Ashrafian**[151] BA MA BM BCh MRCP DPhil
Associate Professor of Medicine, Head of Experimental Therapeutics, Honorary Consultant Cardiologist, Radcliffe Department of Medicine, University of Oxford

**Dr Susan Benbow** MBChB MD FRCP
Consultant Physician in Diabetes and Endocrinology & Clinical Head of Medicine, Diabetes Centre, Aintree University Hospital NHS Trust, Liverpool

**Professor Rudolf W Bilous**[152] MD FRCP
Professor of Clinical Medicine (Diabetes), James Cook University, Middlesbrough

**Professor Peter M A Calverley**[153] MB ChB JCHMT FRCP FRCPE FMedSci
Emeritus Professor of Medicine (Pulmonary and Rehabilitation Medicine), University of Liverpool

**Dr Steven Cunningham**[154] PhD FRCPCH FRCP
Consultant Respiratory Paediatrician, Royal Hospital for Sick Children, Edinburgh

**Professor Richard Donnelly** MD PhD FRCP FRACP
Professor in Medicine and Head, School of Graduate-Entry Medicine, University of Nottingham

**Dr Iolo J Doull** MRCP DM FRCPCH
Consultant Respiratory Paediatrician, Respiratory/Cystic Fibrosis Unit, Children's Hospital for Wales, Cardiff

**Dr John Firth**[155] BA BM ChB DM FRCP
Consultant Physician and Nephrologist, Addenbrooke's Hospital, Cambridge

**Dr Andrew Grace**[156] MB PhD FRCP FACC FESC
Consultant Cardiologist, Papworth and Addenbrooke's Hospitals Cambridge & Research Group Head, Department of Biochemistry, University of Cambridge

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[151] Appointed 14 November 2013 - 13 November 2017
[152] Resigned 7 January 2013
[153] Appointed 15 February 2013 - 14 February 2017
[154] Appointment ended 11 November 2013
[155] Re-appointed 10 December 2013 - 9 December 2017
[156] Re-appointed 12 November 2013 - 11 November 2017

**Professor Richard I G Holt**[157] MA MB BChir PhD FRCP FHEA
Professor in Diabetes & Endocrinology, Human Development and Health Academic Unit, Faculty of Medicines, University of Southampton
Honorary Consultant Physician, University Hospital Southampton NHS Foundation Trust

**Dr Philip W Ind** BA Cantab MB BChir MA Cantab FRCP
Consultant Physician and Honorary Senior Lecturer in Respiratory Medicine, Imperial School of Medicine, Hammersmith Hospital

**Professor Alan G Jardine** BSc MD FRCP
Professor of Renal Medicine, University of Glasgow

**Professor Ann Millar**[158] MBChB MD FRCP **(Vice Chair)**
Professor in Respiratory Medicine, Bristol University & Honorary Consultant North Bristol NHS Trust

**Dr Hilary Pinnock**[159] MB ChB (Hons) MRCGP MD
Reader and Principal in General Practice, Allergy and Respiratory Research Group, University of Edinburgh

**Dr Jonathan Ross**[160] MB ChB FRCA FFICM
Consultant Cardiothoracic Anaesthetist, Sheffield Teaching Hospitals NHS Foundation Trust and Honorary Clinical Senior Lecturer, Anaesthesia, University of Sheffield

**Dr Pallav Shah** MD MBBS FRCP
Consultant Physician, Royal Brompton Hospital, and Chelsea & Westminster Hospital, Reader in Respiratory Medicine Imperial College

**Dr Michael J Stewart**[161] MB ChB MD FRCP(Ed) FRCP
Consultant Cardiologist, James Cook University Hospital, Middlesbrough

**Dr Caroline L Vaughan**[162] PhD
Lay Representative of MHRA EAGS. Trustee and Director of Contact a Family and FamilyLine

**Mr Phil Willan**[163] MSc
Lay Representative. Member of the Royal College of Physicians' (RCP) Patient and Carer Network; Member of the RCP Joint Speciality Committee (JSC) for Renal Medicine, Healthcare Associated Infections Working Group, Specialist Advisory Committee for Renal Medicine, JSC for Allergy and Immunology, Faculty of Forensic and Legal Medicine, Federation CPD Policy Committee and Equality and Diversity Monitoring Committee

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[157] Appointed 12 December 2013 - 11 December 2017
[158] Re-appointed 12 November 2013 - 11 November 2017
[159] Appointed 15 February 2013 - 14 February 2017
[160] Resigned 3 September 2013
[161] Resigned 5 November 2013
[162] Re-appointed 12 November 2013 - 11 November 2017
[163] Re-appointed 14 January 2013 - 13 January 2017

## MEMBERSHIP OF THE CHEMISTRY, PHARMACY AND STANDARDS EXPERT ADVISORY GROUP

### Remit

To advise the Commission on the quality in relation to safety and efficacy of medicinal products which are the subject of marketing authorisation applications and to advise on such other matters as are referred to it.

### Chair

**Professor Kevin M G Taylor**[164] BPharm PhD FRPharmS
Chair of the British Pharmacopoeia Commission and Professor of Clinical Pharmaceutics, UCL School of Pharmacy, London

### Members

**Professor Michael E Aulton**[165] BPharm PhD FRPharmS FAAPS FSP
Emeritus Professor, De Montfort University, Leicester

**Professor Graham Buckton**[166] BPharm PhD DSc FRPharmS FRSC
Professor of Pharmaceutics, UCL School of Pharmacy

**Professor Derek H Calam**[167] OBE MA DPhil Hon DSc CChem FRSC FRSA Hon MRPharmS Hon MTOPRA
Visiting Professor of Pharmaceutical Sciences at the University of Strathclyde

**Professor Brian J Clark**[168] MSc PhD CChem FRSC
Professor of Pharmaceutical and Biomedical Analysis, Bradford University

**Professor Ruth Duncan** PhD
Professor Emerita in Cell Biology and Drug Delivery, Cardiff University and Visiting
Professor at the University of Greenwich

**Professor Gillian M Eccleston**[169] BSc PhD CChem FRSC FRPharmS **(Vice Chair)**
Professor of Pharmaceutics, Strathclyde University

**Mr V'Iain G Fenton-May**[170] BPharm MIPharm FRPharmS
Pharmaceutical Microbiologist

**Professor Geoffrey W Hanlon**[171] BSc PhD MRPharmS
Emeritus Professor of Pharmaceutical Microbiology, School of Pharmacy & Bio-Molecular Sciences, University of Brighton

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[164] Appointed as Chair 15 October 2013 - 31 December 2015
[165] Re-appointed 14 October 2013 - 13 October 2015
[166] Re-appointed 12 November 2013 until 11 November 2015
[167] Stepped down as Chair on 15 October, continued as a Member 1 November 2013 – 30 October 2014
[168] Re-appointed 14 October 2013 – 13 October 2017
[169] Re-appointed 12 November 2013 – 11 November 2015
[170] Re-appointed 12 November 2013 – 11 November 2017
[171] Re-appointed 12 November 2013 – 11 November 2015

**Dr Gillian M Hawksworth** MBE PhD FFRPS FRPharmS (Hon) DSc
Academic Community Pharmacist, Senior Lecturer at University of Huddersfield & Past President of the RPSGB

**Miss Carol E Knott**[172] MRPharmS MBA MIHM
Lay Representative. Director of Windcliff Management Ltd

**Mr Robert A Lowe** BPharmS MRPharmS
Practising Hospital Pharmacist, NHS Eastern Region

**Professor Christopher Marriott**[173] PhD DSc Hon DSc FRPharmS CChem FRSC FRSM
Emeritus Professor of Pharmaceutics, King's College, London

**Professor Yvonne Perrie**[174] BSc Hons MRPharmS FAPS FSB PhD
Head of Pharmacy, Aston University

**Ms Hilary A Shenton** CPFA
Lay Representative. Retired Secretary to the School of Medicine, University of Sheffield

**Professor Michael D Threadgill**[175] PGCE MA PhD DSc FRSC CChem
Professor in Medicinal Chemistry, Department of Pharmacy and Pharmacology, University of Bath

**Professor Peter York** PhD BSc DSc FRPharmS CChem FRSC FAAPS
Emeritus Professor of Pharmaceutics, Bradford University

[172] Re-appointed 14 January 2013 – 13 January 2017
[173] Re-appointed 14 October 2013 – 13 October 2015
[174] Appointed 14 November 2013 – 13 November 2017
[175] Appointed 14 November 2013 – 13 November 2017

## MEMBERSHIP OF THE GASTROENTEROLOGY, RHEUMATOLOGY, IMMUNOLOGY & DERMATOLOGY EXPERT ADVISORY GROUP

### Remit

To advise the Commission on the safety and efficacy of medicines for use in gastroenterological, rheumatological, immunological and dermatological diseases.

### Chair

**Professor Stuart H Ralston**[176] MB ChB MD FRCP FMedSci FRSE
Arthritis Research UK Professor of Rheumatology, University of Edinburgh, Western General Hospital, Edinburgh

**Professor Anthony G Wilson**[177] MB BCH BAO DCH PhD FRCP
Professor of Rheumatology, Medical School, University of Sheffield

### Members

**Dr Ian Barrison** BSc MB FRCP FEBGH
President European Board of Gastroenterology and Hepatology; Associate Dean, Postgraduate Medicine, School of Life and Medical Sciences, University of Hertfordshire

**Professor Deborah Bax** MB ChB MD FRCP (London & Edinburgh)
Consultant Physician in Rheumatology, Hallamshire Hospital, Sheffield; Honorary Professor in Rheumatology, University of Sheffield

**Mrs Alison Bowser**[178]
Lay Representative. Patient and Public Involvement Officer, Research Design Service, Southampton University & National Institute for Health Research

**Mr David Chandler**[179]
Lay Representative. Chief Executive, Psoriasis and Psoriatic Arthritis Alliance, Hertfordshire

**Professor David Gawkrodger** DSc MD FRCP FRCPE **(Vice Chair)**
Professor Emeritus in Dermatology, University of Sheffield
Emeritus Consultant Dermatologist, Sheffield Teaching Hospitals NHS Foundation Trust

**Dr Clive Grattan** BA MA MB BChir FRCP MD ILT
Consultant Dermatologist, Norfolk and Norwich University NHS Trust

**Dr Richard Groves** MB BS MRCP FRCP
Consultant Dermatologist, St John's Institute of Dermatology, Guy's and St Thomas Hospital

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[176] Resigned as Chair 11 February 2013
[177] Appointed as Chair 23 May 2013 – 13 October 2014 (previously appointed as a Member 14 October 2010 – 13 October 2014)
[178] Resigned 20 September 2013
[179] Appointed 17 October 2013 – 16 October 2014

**Professor John D Isaacs** BSc (Hon) MB BS PhD FRCP
Director of the Institute of Cellular Medicine & Professor of Clinical Rheumatology, Medical School, Newcastle University

**Dr John C Mansfield** MA MBBS MD FRCP
Consultant Physician and Senior Lecturer in Gastroenterology, Royal Victoria Infirmary and University of Newcastle upon Tyne

**Professor Kevin Moore** BSc MB BS PhD FRCP
Professor of Hepatology, Royal Free Hospital, London

**Dr Frances Williams**[180] BSc MBBS MRCP PhD CCST FRCP (Edin)
Reader in Genetic Epidemiology and Hon Consultant Rheumatologist, King's College London

**Professor Patricia Mang Ming Woo** CBE FRCP FRCPCH FMedSci
Professor of Paediatric Rheumatology and Honorary Consultant, UCL

[180] Appointed 23 May 2013 – 22 May 2017

## MEMBERSHIP OF THE MEDICINES FOR WOMEN'S HEALTH EXPERT ADVISORY GROUP

### Remit

To advise the Commission on the safety and efficacy of medicines related to endocrinology and women's reproductive health from menarche to menopause and conditions related to the menopause, such as osteoporosis. The medicines covered will include medicines for contraception, emergency contraception and termination of pregnancy; medicines for infertility and assisted conception; HRT and non-hormonal treatments for osteoporosis.

### Chair

**Dr Ailsa Gebbie** MB ChB FRCOG FRCPE FFSRH
Consultant Gynaecologist and Deputy Director, Chalmers Centre, Edinburgh

### Members

**Dr Sarah R Atkinson**[181] MB BS DFSRH
Associate in General Practice, Parkstone Health Centre, Poole, Dorset; Speciality Doctor Contraceptive Health Services, Dorset Healthcare University NHS Foundation Trust

**Professor Dame Valerie Beral**[182] DBE FRS MBBS MD FRCP FRCOG FFPHM FMedSci
Professor of Epidemiology, Cancer Epidemiology Unit, University of Oxford

**Professor Juliet Compston** MD FRCP FRCPath FMedSci
Professor of Bone Medicine & Honorary Consultant Physician, School of Clinical Medicine, Cambridge University

**Dr Katherine Darton** BA BSc PhD LGSM
Lay Member

**Professor Philip Hannaford** MB ChB DRCOG DCH MD FRCGP FFSRH FFPH
Professor of Epidemiology, University of Aberdeen

**Dr Sally Hope**[183] FRCP FRCGP DRCOG
Honorary Research Fellow in Woman's Health, Dept of Primary Health Care, University of Oxford and Clinical Assistant in Osteoporosis at the Nuffield Orthopaedic Hospital, Oxford

**Professor Mary Lumsden**[184] BSc MB BS MD FRCOG **(Vice Chair)**
Professor of Medical Education & Gynaecology, University of Glasgow

**Professor Siobhan Quenby**[185] MBBS BSc MD FRCOG
Professor of Obstetrics, Warwick University

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[181] End of appointment 11 November 2013
[182] Resigned 8 August 2013
[183] Re-appointed 11 November 2013 – 10 November 2015
[184] Re-appointed 12 November 2013 – 11 November 2017
[185] Re-appointed 12 November 2013 – 11 November 2017

**Professor Stuart H Ralston**[186] MB ChB MD FRCP FMedSci FRSE
Arthritis Research UK Professor of Rheumatology, University of Edinburgh, Western General Hospital, Edinburgh

**Mrs Margaret V Shotter**[187] BSc MSc
Lay Member

### Commission on Human Medicines Observer:

**Carolyn, Lady Roberts** RGN RHV MSc DUniv
Member of The Ethox Foundation - Oxford Centre for Ethics and Communication in Healthcare Practice. Healthcare Visitor

### Invited Expert to Meetings:

**Professor Julietta Patnick** CBE
Director, NHS Cancer Screening Programmes, Sheffield & Directorate of Health and Wellbeing, Public Health England

[186] Resigned 11 February 2013
[187] Re-appointed 14 March 2013 – 13 March 2015

## MEMBERSHIP OF THE NEUROLOGY, PAIN & PSYCHIATRY EXPERT ADVISORY GROUP

### Remit

To advise the Commission on the safety and efficacy of medicines for use in neurological conditions, pain management and psychiatric conditions.

### Chair

**Professor David G C Owens**[188] MD FRCP FRCPsych
Professor of Clinical Psychiatry, Edinburgh University

### Members

**Dr Jonathan Cavanagh** MB ChB MPhil MD FRCPsych
Senior Lecturer in Psychiatry, Glasgow University and Honorary Consultant Psychiatrist, NHS Greater Glasgow and Clyde

**Dr Beverley Jane Collett** MB BS FRCA
Consultant in Pain Management & Anaesthesia & Assistant Medical Director, Leicester Royal Infirmary

**Professor John Duncan**[189] BA BMBCh MA (Ox) DM (Ox) FRCP (Lon) FMedSci
Professor of Clinical Neurology, Department of Clinical and Experimental Epilepsy, UCL Institute of Neurology; Clinical Director, Queen Square Division, UCLH NHS Foundation Trust

**Dr Nicholas Fletcher**[190] BSc MBBS MD FRCP
Consultant Neurologist Walton Centre for Neurology & Neurosurgery, Liverpool

**Professor John Geddes**[191] MD FRCPsych
Professor of Epidemiological Psychiatry, Warneford Hospital

**Mr Michael Harnor**[192] MSc MEd
Lay Representative, National Chairman - British Epilepsy Association (Epilepsy Action), Chair - The Greater Manchester Neurological Alliance

**Dr Anthony L Johnson** BSc PhD CStat
Senior Medical Statistician, MRC Clinical Trials Unit at UCL, London

**Professor Malcolm R Macleod**[193] BSc MBChB MRCP PhD FRCP (Edin)
Professor of Neurology and Translational Neurosciences, University of Edinburgh and Honorary Consultant Neurologist, NHS Forth Valley

**Professor John T O'Brien**[194] BA MA BMBCh DM FRCPsych
Professor of Old Age Psychiatry, University of Cambridge

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[188] Appointed 18 April 2013 – 31 December 2015
[189] Re-appointed 12 November 2013 – 11 November 2015
[190] Re-appointed 12 November 2013 – 11 November 2015
[191] Resigned 28 November 2013
[192] Re-appointed 12 November 2013 – 11 November 2015
[193] Appointed 18 April 2014 – 17 April 2107
[194] Re-appointed 12 November 2013 – 11 November 2015

**Professor Martin Rossor** BChir MA MB MD FRCP FMedSci
Professor of Neurology, Institute of Neurology, London

**Professor Peter A G Sandercock**[195] MA DM FRCP (Edin) FMedSci
Professor of Medical Neurology and Honorary Consultant Neurologist, University of Edinburgh

**Dr Catherine F Stannard** MB ChB FRCA FFPMRCA
Pain Clinic Macmillan Centre, Frenchay Hospital Bristol

**Professor Eric A Taylor** BA MA MB BChir MRCP MRCPsych FRCP FMedSci
Emeritus Professor of Child & Adolescent Psychiatry, King's College London Institute of Psychiatry

**Dr Christopher Weir** BSc (Hons) PhD MSc FRSS C.Stat C. Sci
Reader in Medical Statistics, Centre for Population Health Sciences, University of Edinburgh

**Dr John B Winer** MB BS MRCP MSc (Immuno) MD FRCP
Consultant Neurologist, Queen Elizabeth Hospital, Birmingham

[195] Appointed 18 April 2013 – 17 April 2017

## MEMBERSHIP OF THE ONCOLOGY AND HAEMATOLOGY EXPERT ADVISORY GROUP

### Remit

To advise the Commission on the safety and efficacy of medicines of use in the treatment of malignant disease or blood disorders.

### Chair

**Professor John F Smyth**[196] MD FRCP FRCS FRCR FRSE
Emeritus Professor of Medical Oncology, University of Edinburgh

**(Acting) Dr Angela E Thomas**[197] MB BS PhD FRCP FRCPath FRCPCH
Consultant Paediatric Haematologist, Royal Hospital for Sick Children, Edinburgh

### Members

**Mrs Eileen J Barrett** BSc PGCE
Head of Legal and Employment, Source BioScience, Nottingham

**Professor Mark D Bower** MA MB BChir PhD FRCP FRCPath
Consultant Medical Oncologist, Chelsea & Westminster Hospital, London

**Dr Chris Gallagher** BSc PhD FRCP
Consultant Medical Oncologist, St Bartholomew's Hospital, Barts and the London NHS Trust

**Professor Martin Gore**[198] MBBS PhD FRCP
Medical Director and Consultant Medical Oncologist, The Royal Marsden NHS Foundation Trust and Professor of Cancer Medicine Institute of Cancer Research

**Professor Charlie Gourley** BSc (Hons) MB ChB PhD MRCP FRCP
Professor and Honorary Consultant in Medical Oncology, University of Edinburgh Cancer Research Centre

**Professor John Gribben** BSc (Hons) MBChB MD FRCPath DSc FRCP FMedSci
Professor of Medical Oncology, Director of Experimental Cancer, Medicine Centre Barts and the London Cancer Centre

**Professor Barry W Hancock** OBE MBChB DCH MD FRCP FRCR
Emeritus Professor of Oncology, University of Sheffield

**Professor Peter Hillmen** MB ChB PhD FRCPath
Consultant Haematologist, St James's University Hospital, Leeds

**Professor Clive W Mulholland**[199] BSc PhD CSci FIBMS SFHEA FRSA
Deputy Vice Chancellor, University of South Wales – Lay Representative

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[196] Retired 18 July 2013
[197] Appointed as Acting Chair 19 July 2013
[198] Appointed 23 May 2013 – 22 May 2017
[199] Appointment ended 13 January 2013

## MEMBERSHIP OF THE PAEDIATRIC MEDICINES EXPERT ADVISORY GROUP

### Remit

To advise the Commission on the safety, quality and efficacy of medicines for paediatric use, including all matters relating to the implementation of the EU Paediatric Regulation.

### Chair

**Professor Rosalind L Smyth**[200] MA MBBS MD FRCPCH FFPM (Hon) FMedSci
Director, UCL Institute of Child Health, London

### Members

**Dr Eileen M Baildam**[201] MB ChB DRCOG DCH RCP FRCP FRCPCH
Consultant Paediatric Rheumatologist, Alder Hey Children's NHS Foundation Trust

**Dr Steven Cunningham**[202] PhD FRCPCH FRCP
Consultant Respiratory Paediatrician, Royal Hospital for Sick Children, Edinburgh

**Professor Ruth Gilbert**[203] MB ChB MSc MD FRCPCH
Professor of Clinical Epidemiology, UCL Institute of Child Health

**Professor Peter C Hindmarsh**[204] BSc MD FRCP FRCPCH
Consultant Paediatric Endocrinologist, Royal Free and University College Medical School

**Professor Nigel Klein** BSc MBBS MRCP PhD FRCPCH
Consultant, Great Ormond Street Hospital for Children NHS Trust;
Professor of Infectious Diseases and Microbiology, Institute of Child Health, UCL

**Ms Fiona Lynch** BSc (Hons) MSc RCN
Paediatric Intensive Care Unit Nurse Consultant, Evelina Children's Hospital

**Dr Rebecca Mann**[205] BMBS FRCPCH
Consultant Paediatrician, Taunton and Somerset NHS Foundation Trust

**Professor Marie-Louise Newell**[206] MB MSc PhD FMedSci
Professor of Global Health, Academic Unit of Human Development and Health Faculty of Medicine, University of Southampton

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[200] End of appointment 31 December 2013
[201] Re-appointed 12 November 2013 – 11 November 2017
[202] Re-appointed 12 November 2013 – 11 November 2017
[203] Resigned 25 September 2013
[204] Re-appointed 12 November 2013 – 11 November 2017
[205] Re-appointed 12 November 2013 – 11 November 2017
[206] Appointed 12 December 2013 – 11 December 2017

**Professor Anthony Nunn**[207] BPharm FRPharmS Hon FRCPCH
Honorary Fellow, Department of Women's and Children's Health, University of Liverpool & Industry Professor, School of Pharmacy and Biomedical Sciences, Liverpool John Moores University; Alder Hey Children's Hospital, Liverpool

**Ms Sara Payne** BA CPE LPC
Solicitor – Lay Member

**Professor Shirley Price** MSc PhD FBTS ERT FHEA FSB
Associate Dean of Learning and Teaching, Department of Biochemical and Physiological Sciences, Institute of Biosciences and Medicine, Faculty of Health and Medical Sciences, University of Surrey

**Professor Michael Stevens**[208] MD FRCP FRCPCH FRCR **(Vice Chair)**
Professor of Paediatric Oncology, University of Bristol

**Dr Jane Tizard** MBBS FRCP FRCPCH
Consultant Paediatric Nephrologist, Bristol Royal Hospital for Children

**Dr Catherine L C Tuleu** PhD Cert Ed MRPharmS
Reader in the Department of Pharmaceutics, Director of the Centre for Paediatric Pharmacy Research, UCL School of Pharmacy

**Professor Heather M Wallace** PhD FRCPath FBTS FRSC FSB FBPharmacolS ERT
Professor of Biochemical Pharmacology and Toxicology, Division of Applied Medicine, University of Aberdeen

**Mrs Madeleine Wang** BA (Hons)
Lay Member - Patient Advocate

**Dr William P Whitehouse**[209] BSc MB BS DCH FRCP FRCPCH
Clinical Senior Lecturer in Paediatric Neurology, Department of Child Health, Queen's Medical Centre, Nottingham

**Dr Mark Whiting** BNursing MSc PhD
Consultant Nurse, Children's Community and Specialist Nursing, Peace Children's Centre, Hertfordshire Community NHS Trust

**Professor Andrew Wolf** [210] MB B Chir FFA RCS Eng
Paediatric Anaesthesiology, Intensive Care and Pain Management, Bristol Royal Infirmary

**Dr Geoffrey Wong**[211] MA MD (Res) MBBS MRCGP FHEA
GP Principal and Senior Lecturer in Primary Care, Queen Mary University of London

**Dr Morris Zwi** MB BCh FRCPsych
Consultant Child & Adolescent Psychiatrist, Richmond Royal Hospital

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[207] Re-appointed 12 November 2013 – 11 November 2014
[208] End of appointment 11 November 2013
[209] End of appointment 11 November 2013
[210] End of appointment 11 November 2013
[211] End of appointment 11 November 2013

## MEMBERSHIP OF THE PATIENT AND PUBLIC ENGAGEMENT EXPERT ADVISORY GROUP

### Remit

To advise the Commission on:

- The development of effective communications for patients, the public and carers to help them make informed choices about medicines and to use medicines safely
- How to improve communication between patients and health professionals and between the MHRA and the public on the safe use of medicines
- Ways to promote the availability and accessibility of high quality information about individual medicines available in the UK
- Ways to encourage reporting of adverse drug reactions (ADRs) by patients and the public. Recognising the importance of the patient experience, to advise on building links between patient concerns as experienced in direct ADR reports and the information provided to patients
- Facilitating targeted patient involvement on relevant regulatory issues, where patient/public involvement has not otherwise been achieved by working with specific patient organisations
- Providing a patient perspective on strategic issues such as the upcoming European legislation on Patient Information.

### Chair

**Mr Harry Cayton** OBE
Chief Executive, Professional Standards Authority for Health and Social Care, London

### Members

**Ms Hellen Adom** BA MA
Outreach Assistant, NHS Sickle Cell & Thalassaemia Screening Programme, London

**Professor Tony Avery**[212] B Med Sci (Hons) MB ChB DGM DCH DM FRCGP
Professor of Primary Care, University of Nottingham

**Mr David Chandler**
Chief Executive, Psoriasis and Psoriatic Arthritis Alliance, Hertfordshire

**Mr John Chapman** LL.B (Lon)
Patient/Carer Member

[212] Resigned 26 January 2013

**Mrs Joyce Epstein**
Former Director of the Foundation for the Study of Infant Deaths (FSID)

**Dr Nicola Jane Gray** PhD MRPharmS FHEA FSAHM (US)
Independent Pharmacist Researcher, Manchester

**Ms Amanda Hoey**[213]
Lay Representative. Director, Consumer Health Consulting Ltd

**Mrs Farrah Pradhan**
Patient Insights Advocacy Coordinator RCPCH

**Mrs June Rogers** MBE RN RSCN BA (Hons) MSc
PromoCon Team Director, Disabled Living

**Dr Bella Starling** PhD BSc Hons Dip
Director of Public Programmes, Nowgen, A Centre for Genetics in Healthcare

**Mr Paddy Storrie** MA (Oxon) NPQH
Deputy Headmaster, St. George's School, Hertfordshire and Lay Member, N.I.C.E Technology Appraisals Committee

**Mr Phil Willan** MSc
Lay Representative. Member of the Royal College of Physicians' (RCP) Patient and Carer Network; Member of the RCP Joint Speciality Committee (JSC) for Renal Medicine, Healthcare Associated Infections Working Group, Specialist Advisory Committee for Renal Medicine, JSC for Allergy and Immunology, Faculty of Forensic and Legal Medicine, Federation CPD Policy Committee and Equality and Diversity Monitoring Committee

**Invited External Experts:**

**Professor D K Theo Raynor** BPharm (Hons) PhD MRPharmS
Professor of Pharmacy Practice, University of Leeds

**Mrs Anne Joshua** BPharm (Hons) MSc Pharm Dip MRPharmS
Associate Director of Pharmacy, NHS Direct

[213] Re-appointed 1 January 2013 – 31 December 2014

## MEMBERSHIP OF THE PHARMACOVIGILANCE EXPERT ADVISORY GROUP

### Remit

To advise the Commission on the following in relation to human medicines including herbal products:

- the public health importance of potential new safety signals
- the confirmation and quantification of risks identified
- appropriate risk minimisation measures including communications
- design and progress of pharmacovigilance plans
- methodologies for pharmacovigilance.

### Chair

**Professor Munir Pirmohamed** MB ChB (Hons) PhD FRCP FRCP (Edin) FMedSci
Professor of Clinical Pharmacology, University of Liverpool, NHS Chair of Pharmacogenetics and Director of the Wolfson Centre for Personalised Medicine

### Members

**Dr Robert C G Bracchi** BSc MB Bch MD FRCGP
General Practitioner, Honorary Senior Lecturer, School of Medicine, Cardiff University

**Dr Jamie Coleman** ChB MD MA (Med Ed) MRCP(UK)
Senior Lecturer in Clinical Pharmacology, University Hospitals Birmingham NHS Foundation Trust, Queen Elizabeth Hospital Birmingham

**Dr William Dixon** MRCP PhD
MRC Clinician Scientist and Honorary Consultant Rheumatologist, The University of Manchester

**Dr Ian J Douglas** BSc MSc PhD
Lecturer in Pharmacoepidemiology, London School of Hygiene & Tropical Medicine

**Ms Alison B Ewing** BSc MSc MIPharmM FFRPS FRPharmS
Clinical Director of Pharmacy, Royal Liverpool and Broadgreen University Hospital NHS Trust

**Professor David Gunnell**[214] MB ChB MRCGP PhD MSc FFPHM
Professor of Epidemiology, University of Bristol

**Professor Glyn Lewis**[215] BA MSc MB BS MRCPsych PhD
Professor of Psychiatric Epidemiology, University College London

[214] End of appointment 11 November 2013
[215] Appointed 14 November 2013 – 13 November 2017

**Professor Simon R J Maxwell**[216] MD PhD FRCP FRCPE FBPharmacolS FHEA
Professor of Student Learning/Clinical Pharmacology, Western General Hospital, Edinburgh & University of Edinburgh

**Dr Karen Miller** BSc MBBS DRCOG DCH DFFP MRCGP
GP Partner, Adelaide Medical Centre, London

**Dr Nicholas J Plant**[217] BSc PhD
Senior Lecturer in Molecular Toxicology, University of Surrey

**Mrs Amanda Sherratt** RGN RM RNP MSc (NURS) BSc (Hons) Dip HEd PG Cert ANNP
PhD student, Academic Lecturer Health Professional Studies. University of Hull

**Professor Alan Silman** MRCP MSc MFCM MD FFPHM FRCP FMedSci
Medical Director of the Arthritis Research Campaign

**Dr Ruben Thanacoody** MD FRCP (Edin)
Consultant Physician and Clinical Toxicologist, Royal Victoria Infirmary, Newcastle-upon-Tyne

**Dr Caroline L Vaughan**[218] PhD
Lay Representative of MHRA EAGS. Trustee and Director of Contact a Family and FamilyLine

**Professor Patrick Waller** BMedSci MD MPH FRCP Ed. FFPM FBPharmacolS
Honorary Professor, Faculty of Epidemiology and Public Health, London School of Hygiene and Tropical Medicine

**Mr Phil Willan**[219] MSc
Lay Representative. Member of the Royal College of Physicians' (RCP) Patient and Carer Network; Member of the RCP Joint Speciality Committee (JSC) for Renal Medicine, Healthcare Associated Infections Working Group, Specialist Advisory Committee for Renal Medicine, JSC for Allergy and Immunology, Faculty of Forensic and Legal Medicine, Federation CPD Policy Committee and Equality and Diversity Monitoring Committee

[216] Re-appointed 10 December 2013 – 9 December 2017
[217] Re-appointed 10 December 2013 – 9 December 2017
[218] Re-appointed 12 November 2013 – 11 November 2017
[219] Re-appointed 14 January 2013 – 13 January 2017

## THE COMMISSION'S WORKING GROUPS:

## MEMBERSHIP OF THE DIANETTE WORKING GROUP

### Chair

**Dr Ailsa Gebbie** MB ChB FRCOG FRCPE FFSRH
Consultant Gynaecologist and Deputy Director, Chalmers Centre, Edinburgh

### Members

**Professor Richard Anderson** MD PhD FRCOG FRCPE
Professor of Clinical Reproductive Science Head of Section, Obstetrics and Gynaecology, MRC Centre for Reproductive Health, Queen's Medical Research Institute, University of Edinburgh

**Professor David Gawkrodger** DSc MD FRCP FRCPE
Professor Emeritus in Dermatology, University of Sheffield; Emeritus Consultant Dermatologist, Sheffield Teaching Hospitals NHS Foundation Trust

**Dr Clive Grattan** BA MA MB BChir FRCP MD ILT
Consultant Dermatologist, Norfolk and Norwich University NHS Trust

**Dr Richard Groves** MB BS MRCP FRCP
Consultant Dermatologist, St John's Institute of Dermatology, Guy's and St Thomas Hospital

**Dr Sally L Hope** FRCP FRCGP DRCOG
Honorary Research Fellow in Woman's Health, Dept of Primary Health Care, University of Oxford and Clinical Assistant in Osteoporosis at the Nuffield Orthopaedic Hospital, Oxford

**Professor Munir Pirmohamed** MB ChB (Hons) PhD FRCP FRCP (Edin) FMedSci
Professor of Clinical Pharmacology, University of Liverpool, NHS Chair of Pharmacogenetics and Director of the Wolfson Centre for Personalised Medicine

**Carolyn, Lady Roberts** RGN RHV MSc DUniv
Member of The Ethox Foundation - Oxford Centre for Ethics and Communication in Healthcare Practice. Healthcare Visitor

**Mrs Margaret V Shotter** BSc MSc
Lay Member

**Dr P C Connie Smith** MB BS MFSRH
Consultant in Sexual and Reproductive Health Care, Westminster PCT

## MEMBERSHIP OF THE INSULINS WORKING GROUP

### Chair

**Dr Amanda Adler** MD PhD
Consultant Physician, Clinical Lead Diabetes Institute of Metabolic Science Wolfson Diabetes & Endocrine Clinic, Addenbrooke's Hospital, Cambridge University Hospitals

### Members

**Dr Susan Benbow** MBChB MD FRCP
Consultant Physician in Diabetes and Endocrinology & Clinical Head of Medicine, Diabetes Centre, Aintree University Hospital NHS Trust, Liverpool

**Professor Rudolf W Bilous** MD FRCP
Professor of Clinical Medicine (Diabetes), James Cook University, Middlesbrough

**Professor Helen Colhoun** MD MFPHM FRCP (Edin)
Professor of Public Health, University of Dundee and Honorary Consultant, Public Health NHS Fife

**Professor Richard Donnelly** MD PhD FRCP FRACP
Professor in Medicine and Head, School of Graduate-Entry Medicine, University of Nottingham

**Professor B Kevin Park** BSc PhD FMedSci FRCP (Hon) FBTS
Director of MRC Centre for Drug Safety Science, Professor of Pharmacology & Head of Institute of Translational Medicine, University of Liverpool

**Professor Anthony Swerdlow** FMedSci
Professor of Epidemiology, Institute of Cancer Research

**Professor Norman Waugh**[220] MB ChB DA MRCP (UK) MPH MFPHM
Professor in Public Health, Warwick Medical School

**Professor Ian V D Weller** BSc MB BS MD FRCP (Hon) FRCP (Glas)
Emeritus Professor of Sexually Transmitted Diseases, University College London Medical School

**Dr Geoffrey Wong** MA MD (Res) MBBS MRCGP FHEA
GP Principal and Senior Lecturer in Primary Care, Queen Mary University of London

[220] Resigned 04/03/13

## MEMBERSHIP OF THE NATIONAL EMERGENCY STOCKPILE QUALITY PANEL

### Chair

**Professor Stuart Ralston** MB ChB MD FRCP FMedSci FRSE
Arthritis Research UK Professor of Rheumatology, University of Edinburgh, Western General Hospital, Edinburgh

### Members

**Dr Barbara A Bannister** MBE MSc FRCP **(Vice Chair)**
Consultant in Infectious and Tropical Diseases, Royal Free Hospital, London

**Professor Derek H Calam** OBE MA DPhil Hon DSc CChem FRSC FRSA Hon MRPharmS Hon MTOPRA
Visiting Professor of Pharmaceutical Sciences at the University of Strathclyde

**Professor Janet H Darbyshire** CBE MB ChB FMedSci FRCP FFPH FRSS (Hon)
Emeritus Professor of Epidemiology, University College London

**Dr Stephen C Inglis**[221] BSc PhD
Director, National Institute for Biological Standards and Control (NIBSC)

**Professor B Kevin Park** BSc PhD FMedSci FRCP (Hon) FBTS
Director of MRC Centre for Drug Safety Science, Professor of Pharmacology & Head of Institute of Translational Medicine, University of Liverpool

**Professor Munir Pirmohamed** MB ChB (Hons) PhD FRCP FRCP (Edin) FMedSci
Professor of Clinical Pharmacology, University of Liverpool, NHS Chair of Pharmacogenetics and Director of the Wolfson Centre for Personalised Medicine

**Dr Angela E Thomas** MB BS PhD FRCP FRCPath FRCPCH
Consultant Paediatric Haematologist, Royal Hospital for Sick Children, Edinburgh

[221] Stepped down from MHRA Committees 31/03/13

## MEMBERSHIP OF THE NICOTINE CONTAINING PRODUCTS WORKING GROUP

### Chair

**Professor Ian V D Weller** BSc MB BS MD FRCP (Hon) FRCP (Glas)
Emeritus Professor of Sexually Transmitted Diseases, University College London Medical School

### Members

**Ms Deborah Arnott** MBA FRCP (Hon)
Chief Executive, Action on Smoking & Health

**Professor Deborah Ashby** OBE BSc MSc PhD CStat Hon. MFPHM Hon. MRCR FMedSci
Professor of Medical Statistics and Clinical Trials Co-Director of Imperial Clinical Trials Unit, School of Public Health, Imperial College London

**Professor Paul Aveyard** PhD MRCP MRCGP FFPH
Professor of Behavioural Medicine, University of Oxford

**Professor John R Britton** MB BS MD FRCP FFPHM
Professor of Epidemiology and Director, UK Centre for Tobacco Control Studies, Head of Division of Epidemiology and Public Health, University of Nottingham

**Professor Brian J Clark** MSc PhD CChem FRSC
Professor of Pharmaceutical and Biomedical Analysis, Bradford University

**Ms Amanda Hoey**
Lay Representative. Director, Consumer Health Consulting Ltd

**Professor Martin Jarvis**
Emeritus Professor of Health Psychology, Department of Epidemiology & Public Health, University College London

**Dr Mike Knapton** MA (cantab) MBBChir FRCGP
Associate Medical Director (Prevention & Care), British Heart Foundation

**Professor Christopher Marriott** PhD DSc Hon DSc FRPharmS CChem FRSC FRSM
Emeritus Professor of Pharmaceutics, King's College, London

**Professor Marcus Munafò** MA (Oxon) MSc PhD (Soton)
Professor of Biological Psychology, University of Bristol

**Dr Nicholas J Plant** BSc PhD
Senior Lecturer in Molecular Toxicology, University of Surrey

**Dr Rosalind Ranson** MB BS MA MRCGP
General Practitioner, Woodside Health Centre, London

**Carolyn, Lady Roberts** RGN RHV MSc DUniv
Member of The Ethox Foundation - Oxford Centre for Ethics and Communication in Healthcare Practice. Healthcare Visitor

**Professor Liam Smeeth**
Head of Department, Non-Communicable Disease Epidemiology

## MEMBERSHIP OF THE REVIEW OF NON-PRESCRIPTION ANALGESICS WORKING GROUP

### Chair

**Professor Stuart Ralston** MB ChB MD FRCP FMedSci FRSE
Arthritis Research UK Professor of Rheumatology, University of Edinburgh, Western General Hospital, Edinburgh

### Members

**Mrs Alison Bowser**
Lay Representative. Patient and Public Involvement Officer, Research Design Service, Southampton University & National Institute for Health Research

**Dr William Dixon** MRCP PhD
MRC Clinician Scientist and Honorary Consultant Rheumatologist, The University of Manchester

**Dr Ian J Douglas** BSc MSc PhD
Lecturer in Pharmacoepidemiology, London School of Hygiene & Tropical Medicine

**Dr J Colin Forfar** BSc (Hons) MBChB PhD MD MA FRCP FRCP (Edin)
Consultant Physician and Cardiologist, John Radcliffe Hospital, Oxford

**Dr Gillian M Hawksworth** MBE PhD FRPharmS (Hon) DSc FCPP (Hon)
Academic Community Pharmacist, Visiting Professor of Pharmacy at Huddersfield University & Past President of the RPSGB

**Dr Karen Miller** BSc MBBS DRCOG DCH DFFP MRCGP
GP Partner, Adelaide Medical Centre, London

**Professor Munir Pirmohamed** MB ChB (Hons) PhD FRCP FRCP (Edin) FMedSci
Professor of Clinical Pharmacology, University of Liverpool, NHS Chair of Pharmacogenetics and Director of the Wolfson Centre for Personalised Medicine

**Carolyn, Lady Roberts** RGN RHV MSc DUniv
Member of The Ethox Foundation-Oxford Centre for Ethics and Communication in Healthcare Practice. Healthcare Visitor

**Professor Kevin M G Taylor** BPharm PhD MRPharmS
Chair of the British Pharmacopoeia Commission and Professor of Clinical Pharmaceutics, UCL School of Pharmacy, London

### Invited External Experts:

**Professor Colin Baigent** FFPH FRCP
Professor of Epidemiology and Honorary Consultant in Public Health

**Dr Rebecca Mann** BM BS FRCPCH
Consultant Paediatrician, Taunton and Somerset NHS Foundation Trust

**Invited Observers:**

**Ms Gul Root**
Department of Health

**Professor Neal Maskrey**
National Institute for Health and Care Excellence

**Mr Jonathan Underhill**
National Institute for Health and Care Excellence

**Appendix III**

## MEMBERSHIP OF THE EXTERNAL EXPERT ADVISORY PANEL

### Anaesthesia

**Dr Andrew Bowhay** MBBS FRCA MA
Consultant Paediatric Anaesthesia, Liverpool University

**Dr Thomas Clutton-Brock** FRCP FRCA FFICM
Senior Lecturer, Anaesthesia & Intensive Care Medicine

**Dr Patricia Richardson** BM MRCP FRCA
Consultant in Burns Anaesthesia and Intensive Care, Broomfield Hospital, Chelmsford, Essex

**Dr Jonathan Ross** MB ChB FRCA FFICM
Consultant Cardiothoracic Anaesthetist, Sheffield Teaching Hospitals NHS Foundation Trust and Honorary Clinical Senior Lecturer, Anaesthesia, University of Sheffield

**Dr Lindsey Rylah** MBA FRCA
Consultant Anaesthetist, Basildon Hospital, Essex

**Dr Neil Soni** MB ChB FRCA FANZCA MD FFICANZCA
Consultant in Anaesthesia and Intensive Care, Chelsea and Westminster Hospital, London

### Diabetology/Endocrinology

**Professor D John Betteridge** BSc PhD MD FRCP FAHA
Professor of Endocrinology and Metabolism, University College London, London

**Professor Peter Clayton** MD MRCP FRCPCH
Professor of Child Health & Paediatric Endocrinology; Director, NIHR Greater Manchester, Lancashire & South Cumbria Medicines for Children Research Network

**Professor Paul Stewart** MB ChB MD FRCP FMedSci
Dean & Professor of Medicine, University of Leeds

### Gastroenterology

**Dr Harriet Mitchison** MBBS MA MD FRCP
Consultant Gastroenterologist, District General Hospital, Sunderland

### Geriatric Medicine

**Professor Peter Crome** MD PhD DSc FRCP (Lon, Edin and Glas) FFPM
Professor of Geriatric Medicine, Keele University and Consultant Geriatrician, North Staffordshire Combined Healthcare NHS Trust

### Gynaecology/Family Planning/Well Woman/Obstetrics

**Dr Alistair R W Williams** MD Ed MB ChB Ed. MRCP FRCPath
Reader and Head of Service, Pathology, University of Edinburgh

### Haematology

**Professor Gordon Cook** MB ChB PhD FRCP (Glas) FRCPath FRCPI
Consultant Haematologist and Myeloma Lead, St James's Institute of Oncology, Leeds Teaching Hospitals Trust

### Infectious Diseases/Tropical Medicine

**Professor David Warrell**[222] MA DM DSc FRCP FRCPE FMedSci
International Director (Hans Sloane Fellow), Royal College of Physicians; Emeritus Professor of Tropical Medicine, Hon Fellow St Cross College, University of Oxford

### Liver/Lipidology

**Professor Gilbert Thompson** MD FRCP
Emeritus Professor of Clinical Lipidology, Division of Investigative Science, Imperial College School of Medicine, London

### Medicine (General)

**Professor Jayne Franklyn** MD PhD FRCP FMedSci
William Withering Professor of Medicine; Head, School of Clinical and Experimental Medicine; College of Medical and Dental Sciences

**Professor Paul Stewart** MB ChB MD FRCP FMedSci
Dean & Professor of Medicine, University of Leeds

### Neurology

**Professor Colin Kennedy** MD FRCP FRCPCH
Professor in Neurology and Paediatrics, University of Southampton

**Dr Robin Grant** MBChB MD FRCP (Glas) FRCP (Edin)
Consultant NHS Neurologist and Part-Time Senior Lecturer, Centre for Neuro-Oncology, Western General Hospital, Edinburgh

### Nurse

**Professor Karen Luker** BNurs PhD FMedSci
Head of the School of Nursing, Midwifery and Social Work

### Oncology

**Professor Hugh MacDougall** MBChB DMRT FRCS FRCR FRCPE
Dean of the Faculty of Medicine and Head of the School of Medicine, School of Medicine, University of St Andrews

[222] Stepped down from Panel 31 December 2013

### Orthopaedics

**Mr Keith Tucker** MB BS FRCS
Consultant Orthopaedic Surgeon

### Palliative Medicine/Pain Management

**Professor Karen Forbes** MB ChB FRCP Dip Pall Med Cert Med Ed MILT
Consultant and Macmillan Professorial Teaching Fellow in Palliative Medicine, Bristol Haematology and Oncology Centre

### Paediatricians

**Dr Andrew Bowhay** MBBS FRCA MA
Consultant Paediatric Anaesthesia, Liverpool University

**Professor Peter Clayton** MD MRCP FRCPCH
Professor of Child Health & Paediatric Endocrinology; Director, NIHR Greater Manchester, Lancashire & South Cumbria Medicines for Children Research

**Professor Nedim Hadzic** MD MSc FRCPCH
Professor of Paediatric Hepatology, King's College Hospital

**Dr Nigel Hoggard** MBBChir MD MRCP FRCR
Consultant Neuroradiologist/Clinical Senior Lecturer, Royal Hallamshire Hospital

**Professor Colin Kennedy** MD FRCP FRCPCH
Professor in Neurology and Paediatrics, University of Southampton

**Professor Shakeel Qureshi** MB ChB FRCP
Consultant Paediatric Cardiologist, Guy's Hospital, London

**Professor Alan Smyth** MA MBBS MRCP MD FRCPCH
Professor of Child Health & Head of Division of Child Health, Obstetrics & Gynaecology (COG), University of Nottingham

**Dr John H Walter**[223] MD FRCP FRCPCH
Consultant Paediatrician, Royal Manchester Children's Hospital

**Dr Christopher Wren** MB ChB
Consultant Paediatric Cardiologist, Department of Paediatric Cardiology, Freeman Hospital

### Pathologists/Histopathology/Biology/Immunobiology

**Dr Alistair R W Williams** MD Ed MB ChB Ed. MRCP FRCPath
Reader and Head of Service, Pathology, University of Edinburgh

**Professor Sir Nicholas Wright** MA MD PhD DSc FRCPath
Deputy Principal, Hammersmith Hospital London

[223] Stepped down from Panel 31 December 2013

### Pharmacokinetics

**Professor Leon Aarons** BSc (Hons) MSc PhD
Professor of Pharmacometrics, School of Pharmacy and Pharmaceutical Sciences, Manchester University

**Professor Amin Rostami** PharmD PhD FCP
Professor of Systems Pharmacology, School of Pharmacy and Pharmaceutical Sciences Manchester University

**Dr Alison Thomson** BSc MSc PhD
Area Pharmacy Specialist, Western Infirmary & Strathclyde Institute of Pharmacy & Biomedical Sciences, University of Strathclyde

### Radiology/Nuclear Medicine

**Professor Paul Griffiths** MBChB PhD FRCR
Professor of Radiology & Head of Dept of Academic Unit of Radiology, University of Sheffield, Royal Hallamshire Hospital, Sheffield

**Professor Jonathan Hill** FRCP FRCR
Consultant in Radiology & Nuclear Medicine, Lancashire Teaching Hospitals and Hon Professor of Radionuclide Radiology University of Salford

**Dr Nigel Hoggard** MBBChir MD MRCP FRCR
Consultant Neuroradiologist/Clinical Senior Lecturer, Royal Hallamshire Hospital

**Mr Paul Maltby** CSci MIPEM MRPharmS
Principal Radiopharmacist, Merseyside & Cheshire, Royal Liverpool University Hospital

**Professor Michael O'Doherty** BA MBBS MRCP MSc MD FRCP
Consultant in Nuclear Medicine, Guy's & St Thomas Hospital, London

**Dr Andrew Scarsbrook** BM BS B Med Sci FRCR
Consultant Radiologist & Nuclear Medicine Physician, St James's University Hospital, Leeds

### Renal Medicine/Nephrology

**Professor Stephen Powis** BSc (Hons) BM BCh PhD FRCP
Professor of Renal Medicine and Medical Director, Centre for Nephrology, University College London, Royal Free Hospital, London

**Dr David Wheeler** MD FRCP
Reader in Nephrology, Royal Free Hospital School of Medicine, University College London

### Respiratory Medicine

**Professor Alan Smyth** MA MBBS MRCP MD FRCPCH
Professor of Child Health & Head of Division of Child Health, Obstetrics & Gynaecology (COG), University of Nottingham

### Rheumatology

**Professor David Isenberg** MD FRCP
Academic Director of Rheumatology, University College London

**Professor Roger Sturrock** B.D. MD FRCP
Emeritus Professor of Rheumatology and Hon. Senior Research Fellow, Centre For Rheumatic Diseases

### Urology

**Professor Christopher Chapple** BSc MD FRCS (Urol) FEBU
Consultant Urological Surgeon, Royal Hallamshire Hospital; Honorary Professor of Urology, University of Sheffield; Visiting Professor of Urology, Sheffield Hallam University; Chairman, International Relations Office, European Association of Urology

**Professor Freddie Hamdy** MB ChB LRCP-LRCS (Ed) LRCPS (Glas) FRCS (Ed) MD (Shef) FRCS (Ed) (Urol) FMed Sci
Consultant Urological Surgeon at Oxford Radcliffe Hospitals NHS Trust, Nuffield Professor of Surgery and Professor of Urology

**Mr David Tolley**[224] MB FRCS FRCS(Ed)
Consultant Urological Surgeon and Honorary Senior Lecturer, Lothian University Hospitals NHS Trust, Director, The Scottish Lithotriptor Centre, Western General Hospital, Edinburgh, Spire Murrayfield Hospital Edinburgh and Spire Shawfair Park Hospital

**Professor Robert Pickard** MD FRCS (Urol)
Professor of Urology, Institute of Cellular Medicine, Newcastle University

[224] Stepped down from Panel 31 December 2013

## MEMBERSHIP OF THE OPHTHALMIC EXTERNAL EXPERT PANEL

### Members

**Dr Sajjad Ahmad** FRCOphth PhD
Consultant Ophthalmic Surgeon and Senior Clinical Lecturer

**Mr Bruce Allan** MD FRCS FRCOphth
Consultant Ophthalmic Surgeon, Moorfields Eye Hospital, London

**Mr Ejaz Ansari** BSc (Hons) MBBCh FRCOphth MD
Consultant Ophthalmic Surgeon, Maidstone and Tunbridge Wells NHS Trust

**Professor Paul N Bishop** B Med Sci (Hons) BM BS DO FRCS FRCOphth PhD
Professor of Ophthalmology & Matrix Biology; Head of Centre for Ophthalmology and Vision Research, Institute of Human Development, University of Manchester; Consultant Ophthalmologist, Manchester Royal Eye Hospital, CMFT

**Professor Usha Chakravarthy**[225] MBBS FRCS FRCOphth PhD
Professor of Ophthalmology and Vision Science, Queens University, Belfast & Consultant Ophthalmologist, Belfast Trust

**Professor Charles Claoué** MA (Cantab) MD DO FRCS FRCOphth FEBO MAE
Consultant Ophthalmic Surgeon - 119 Harley Street, London W1G 6AU
Consultant Ophthalmic Surgeon - Queen's Hospital, BHR University Hospitals NHS Trust
Treasurer: International Society of Bilateral Cataract Surgeons www.isbcs.org

**Professor Baljean Dhillon** BMed Sci BM BS FRCP (Glas) FRCS (Edin) FRCOphth
Princess Alexandra Eye Pavillion, Edinburgh

**Ms Cecilia H Fenerty** MD FRCOphth
Consultant Ophthalmologist, Royal Eye Hospital, Manchester

**Mr Philip G Hykin** FRCS FRCOphth
Consultant Ophthalmic Surgeon, Moorfields Eye Hospital, London

**Mr Teifion Emlyn James** FRCP FRCS FRCOpth
Consultant Ophthalmologist (Uveitis), Calderdale Royal Hospital, Department of Ophthalmology Halifax

**Professor Sir Peng T Khaw** PhD FRCP FRCS FRCOphth CBiol FSB FRCPath FMedSci
Professor of Glaucoma and Ocular Healing, and Consultant Ophthalmic Surgeon

**Mr Anthony King** MD MMedSci FRCOphth
Consultant Ophthalmologist, Department of Ophthalmology, Queens Medical Centre, Nottingham

**Mr Martin McKibbin** MB BS FRCOphth
Consultant Ophthalmologist, St James University Hospital, Leeds

[225] Stepped down from panel 31 December 2013

**Professor Sunil Shah** MB BS FRCOphth FRCSE FBCLA
Professor of Ophthalmology & Consultant Ophthalmic Surgeon, England Foundation Trust, Birmingham and Midland Eye Centre and the Midlands Eye Institute

# COMMISSION ON HUMAN MEDICINES/EXPERT ADVISORY GROUPS SECRETARIAT

## Commission on Human Medicines (CHM)

**Dr G Markey** (until September 2013)
**Dr K Prasad** (from September 2013)
Principal Assessor, Licensing

**Ms S Morgan**
Principal Assessor, Pharmacovigilance

**Ms S Singh**
Secretary

**Ms E Paik**
Assistant Secretary

## Biologicals and Vaccines Expert Advisory Group (BVEAG) (1 January to 17 April 2013)

**Dr J Bonnerjea**
Principal Assessor, Licensing

**Dr P Bryan**
Principal Assessor, VRMM

**Ms E Paik**
Secretary

## Chemistry, Pharmacy and Standards Expert Advisory Group (CPSEAG)

**Dr L A Anderson**
Principal Assessor

**Ms E Agca**
Secretary

## Clinical Trials, Biologicals & Vaccines Expert Advisory Group (CTBVEAG) (18 April to 31 December 2013)

**Dr J Bonnerjea**
Principal Assessor, Licensing (Biologicals)

**Dr Elaine Godfrey**
Principal Assessor, Licensing (Clinical Trials)

**Dr P Bryan**
Principal Assessor, VRMM

**Ms E Paik**
Secretary

## Pharmacovigilance Expert Advisory Group

**Ms C Davies**
Principal Assessor

**Ms E Agca**
Secretary

## GLOSSARY

| | |
|---|---|
| **ADHD** | Attention Deficit Hyperactivity Disorder |
| **ADRs** | Adverse Drug Reactions |
| **AIDS** | Acquired immunodeficiency syndrome |
| **ART** | Assisted Reproductive Technology |
| **ATE** | Arterial Thromboembolic Events |
| **BPC** | British Pharmacopoeia Commission |
| **BVEAG** | Biologicals and Vaccines Expert Advisory Group |
| **CDRRAEAG** | Cardiovascular, Diabetes, Renal, Respiratory and Allergy Expert Advisory Group |
| **CHM** | Commission on Human Medicines |
| **CHMP** | Committee for Medicinal Products for Human Use |
| **COPD** | Chronic Obstructive Pulmonary Disease |
| **CPSEAG** | Chemistry, Pharmacy and Standards Expert Advisory Group |
| **CTEAG** | Clinical Trials Expert Advisory Group |
| **DSU** | Drug Safety Update |
| **EAG** | Expert Advisory Group |
| **EC** | European Commission |
| **EMA** | European Medicines Agency |
| **EMEA** | See EMA |
| **FDA** | Food and Drug Administration |
| **GBS** | Guillain-Barre Syndrome |
| **GPRD** | General Practice Research Database |
| **GRIDEAG** | Gastroenterology, Rheumatology, Immunology & Dermatology Expert Advisory Group |
| **GSL** | General Sales List |
| **HIV** | Human immunodeficiency virus |
| **HPV** | Human Papillomavirus |
| **HRT** | Hormone Replacement Therapy |
| **ICS** | Inhaled Corticosteroids |
| **LA** | Licensing Authority |
| **LABAs** | Long acting β2 agonists |
| **MA** | Marketing Authorisation |
| **MWHEAG** | Medicines for Women's Health Expert Advisory Group |
| **NAC** | N-acetylcysteine |

| | |
|---|---|
| **NPPEAG** | Neurology, Pain & Psychiatry Expert Advisory Group |
| **OHEAG** | Oncology and Haematology Expert Advisory Group |
| **OTC** | Over the Counter |
| **P** | Pharmacy |
| **PAR** | Public Assessment Report |
| **PDCO** | European Paediatric Committee |
| **PEAG** | Pharmacovigilance Expert Advisory Group |
| **PI** | Principal Investigators |
| **PIEAG** | Patient Information Expert Advisory Group |
| **PIL** | Patient Information Leaflet |
| **PIPs** | Paediatric Investigation Plans |
| **PMDD** | Premenstrual Dysphoric Disorder |
| **PMEAG** | Paediatric Medicines Expert Advisory Group |
| **POM** | Prescription Only Medicine |
| **PPEEAG** | Patient and Public Engagement Expert Advisory Group |
| **PPIs** | Proton Pump Inhibitors |
| **PUMA** | Paediatric Use Marketing Authorisation |
| **SAG** | Scientific Advisory Group |
| **SEGA** | Subependymal Giant Cell Astrocytoma |
| **SmPC** | Summary of Product Characteristics |
| **SSRI** | Selective Serotonin Re-uptake Inhibitor |
| **TS** | Tuberous Sclerosis |
| **TSE** | Transmissible Spongiform Encephalopathy |
| **vCJD** | Variant Creutzfeldt-Jakob disease |
| **VTE** | Venous Thromboembolism |
| **WHO** | World Health Organisation |
| **YCCs** | Yellow Card Centres |

# BRITISH PHARMACOPOEIA COMMISSION ANNUAL REPORT FOR 2013

## INTRODUCTION

1. The British Pharmacopoeia Commission, appointed under Part 2 of the Human Medicines Regulations 2012, is responsible under regulation 317(4) of the 2012 Regulations for preparing new editions of the British Pharmacopoeia and the British Pharmacopoeia (Veterinary) and for keeping them up to date. It also provides advice to the United Kingdom delegation to the European Pharmacopoeia Commission, of which the United Kingdom is a member by virtue of its obligations under the Convention on the Elaboration of a European Pharmacopoeia (European Treaty Series No. 50; UK Treaty Series No. 32 (1974) CMND 5763) as amended by the Protocol to the Convention (European Treaty Series No. 134; UK Treaty Series No. MISC 16 (1990) CMND 1133). Under regulation 318(2) of the 2012 Regulations the Commission also selects and devises names to be used at the head of monographs, which are subsequently published as British Approved Names.

## MEMBERSHIP

2. A list of Commissioners during 2013, showing their terms of appointment, is shown in **Appendix I**. Following a successful campaign run by the Department of Health's Non-Executive Appointments Team, Professor Kevin Taylor was appointed as the new Chair for a four year term with effect from 1st October 2013. At the end of the year the following nine members were re-appointed for a two year term with effect from 1st January 2014: Professor Donald Cairns, Mr Barry Capon, Dr Graham Cook, Professor Alastair Davidson, Mr Christopher Goddard, Dr Brian Matthews, Dr Lincoln Tsang, Mrs Josephine Turnbull and Professor Elizabeth Williamson. Following the retirement of Mr Fenton-May at the end of the year, Professor Davidson was appointed as the Vice-Chair with effect from 1st January 2014.

3. A list of members of the supporting Expert Advisory Groups, Panels of Experts and Working Parties for 2013 is given in **Appendix II**. As a consequence of the increase in the work associated with biological products, the status of the Panel of Experts on Biological and Biotechnological Products was changed to that of an Expert Advisory Group.

## CODE OF PRACTICE

4. Members of the British Pharmacopoeia Commission are required to comply with a Code of Practice on Declaration of Interests in the Pharmaceutical Industry. This Code of Practice differs from that applicable to the Commission on Human Medicines in that, with the exception of the Chair, members may continue to hold personal interests in the pharmaceutical industry. Members of the Expert Advisory Groups, Panels of Experts and Working Parties are also required to comply with the Code of Practice. Explanatory Notes clarifying how interests are recorded are included in the British Pharmacopoeia and British Pharmacopoeia (Veterinary).

## RULES GOVERNING PROCEEDINGS

5. During the year the Secretariat worked closely with the Department of Health's legal advisers to develop a set of Rules Governing the Proceedings of the British Pharmacopoeia Commission. The Rules are closely based on those established for the Commission on Human Medicines and cover areas such as the selection and appointment of the Vice-Chair, attendance at meetings, declaration of interests and confidentiality of proceedings. The Rules were formally approved by the Chief Executive of the Medicines and Healthcare Products Regulatory Agency, acting on behalf of the Secretary of State, on 17th December 2013.

## MEETINGS

6. The British Pharmacopoeia Commission met three times during 2013. Fourteen meetings of the Expert Advisory Groups and Panels of Experts were also held during the year. These meetings were held at the Medicines and Healthcare Products Regulatory Agency, 151, Buckingham Palace Road, London SW1W 9SZ. The September 2013 meeting of the British Pharmacopoeia Commission was held at the office of the Department of Health, Skipton House, 80 London Road, London SE1 6LH.

7. Summary Minutes of the meetings of the British Pharmacopoeia Commission and its Expert Advisory Groups and Panels of Experts can be found on the British Pharmacopoeia website (http://www.pharmacopoeia.com).

## SECRETARIAT

8. The British Pharmacopoeia Secretariat is based at the headquarters of the Medicines and Healthcare Products Regulatory Agency (151, Buckingham Palace Road). A list of members of the Secretariat is shown in **Appendix III**.

## LABORATORY

9. The British Pharmacopoeia Laboratory is based at the Laboratory of the Government Chemist (LGC), Queen's Road, Teddington, Middlesex, TW11 0LY. The Laboratory is managed under a collaboration agreement with LGC. The Laboratory Management Board is shown in **Appendix III**.

## COSTS

10. For each meeting that they attend, members of the British Pharmacopoeia Commission are entitled to claim a taxable attendance fee of £325 (Chair's fee, £500.) Members of the Expert Advisory Groups and Panels of Experts are entitled to claim a taxable attendance fee of £200 per meeting attended (Chair's fee, £325). Travel and subsistence is also payable within Department of Health guidelines.

## PROGRESS AND PUBLICATIONS

### British Pharmacopoeia 2013

11. Following publication of the British Pharmacopoeia 2013, three electronic updates were issued providing users with the text of the sixth, seventh and eighth Supplements of the 7th edition of the European Pharmacopoeia.

### British Pharmacopoeia 2014

12. The British Pharmacopoeia 2014 was published in August 2013. This new edition is now available as a package containing the five volumes of the British Pharmacopoeia 2014, the one volume of the British Pharmacopoeia (Veterinary) 2014 and access to the CD-ROM and online versions of both publications.

13. This new edition contains almost 3500 monographs for substances and articles used in the practice of medicine and over 400 infrared reference spectra, together with the customary appendices and supporting material. The effective date of the British Pharmacopoeia 2014 is 1st January 2014.

14. All monographs published within the 7th Edition of the European Pharmacopoeia, as amended by Supplements 7.1 to 7.8, are included either in this edition of the British Pharmacopoeia or, where appropriate, in the associated edition of the British Pharmacopoeia (Veterinary). Monographs of the European Pharmacopoeia are clearly distinguished from those of national origin by means of a chaplet of stars that appears alongside the monograph title. Where appropriate, statements of relevance to UK usage, such as Action and use and the list of BP preparations, have been added to the European Pharmacopoeia monographs.

15. The British Pharmacopoeia 2014 contains 40 new monographs of national origin which were not published in previous editions. These include two new monographs for Traditional Herbal Medicines, one new monograph for a material used in the manufacture of Homoeopathic Preparations, three new monographs for unlicensed formulations and a new monograph for a product prepared by biotechnology (Human Glucagon for Injection).

16. The contents of the British Pharmacopoeia 2014 were updated to refer to the Human Medicines Regulations 2012.

17. Editorial changes were made to monographs for Inhaled Products in accordance with the Inhaled Products Policy document, which is available on the BP website. Further changes to such monographs will be made in future editions of the British Pharmacopoeia.

18. Editorial changes were made to monographs for biological products containing a biological method of Assay. The statements on potency were moved from the Assay to form part of the Definition. This change brings these monographs in line with those for formulated preparations for chemical substances that contain a Content statement within the Definition.

19. Five new Appendices were added to harmonise with the European Pharmacopoeia.

20. Three new Supplementary Chapters were added: Chapter I O (Inhaled Products); Chapter IV Q (Metal Catalyst or Metal Reagent Residues); Chapter V A (Monograph Selection: Unlicensed Medicines).

**British Pharmacopoeia (Veterinary) 2014**

21. The British Pharmacopoeia (Veterinary) 2014 was published as a companion volume to the British Pharmacopoeia 2014 in August 2013. This new edition contains monographs, infrared reference spectra and a number of appendices relating to materials used solely in veterinary medicine. The effective date of the British Pharmacopoeia (Veterinary) 2014 is 1st January 2014.

22. The British Pharmacopoeia (Veterinary) 2014 contains four new monographs of national origin which were not published in previous editions.

23. The contents of the British Pharmacopoeia (Veterinary) 2014 were updated to refer to the Human Medicines Regulations 2012.

24. In order to remove confusion about the intended impurity limits in the monographs for Apramycin Sulfate and the range of Apramycin preparations, the Related substances tests in these monographs were updated.

25. A new Supplementary Chapter has been added (I A (Vet) – Monograph Development: Mechanism) which provides an outline of the mechanism by which monographs are selected and developed for inclusion in the British Pharmacopoeia (Veterinary).

**British Approved Names**

26. Supplement No. 2 to British Approved Names 2012 was published in August 2013, adding 25 new names not previously published.

**cd-rom and BP Online**

27. A new version of the cd-rom containing both the British Pharmacopoeia 2014 and the British Pharmacopoeia (Veterinary) 2014 was issued as a component of the British Pharmacopoeia 2014 package, together with access to the online version of the publications (www.pharmacopoeia.co.uk).

28. A maximum of three BP monographs can be supplied electronically to users on request, together with the necessary supporting information including the Introduction, General Notices, Appendices and Supplementary Chapters.

**Prices and Availability**

29. Details of the prices and availability of the above-mentioned publications are shown in **Appendix IV**.

### Future Publications

30. By the end of 2013 work was progressing on the preparation of the next editions of the British Pharmacopoeia and British Pharmacopoeia (Veterinary). These will be published during 2014 and will have an effective date of 1st January 2015.

31. The British Pharmacopoeia Commission and the European Directorate for the Quality of Medicines & HealthCare signed a co-operation agreement in June 2013. This will facilitate the provision of the European Pharmacopoeia text by electronic transfer and will simplify the reproduction of such text in the British Pharmacopoeia publications.

32. An electronic update to the British Pharmacopoeia 2014 will be issued in early 2014 providing users with the text of the 8th Edition of the European Pharmacopoeia which came into effect on 1st January 2014. Further updates will be issued to coincide with the implementation of Supplements 8.1 and 8.2 on 1st April and 1st July 2014 respectively. These updates will only be available via the online BP. The texts will subsequently be included in the BP 2015 publications.

## OTHER PHARMACOPOEIAL MATTERS

### BP Website

33. The Secretariat has continued to add to the content of the British Pharmacopoeia website (http://www.pharmacopoeia.com), including the provision of draft new and revised monographs for comment and the inclusion of chromatograms to support new monographs published in the British Pharmacopoeia 2014.

34. The site has increased the amount of information available to both the public and users of the British Pharmacopoeia and has provided greater transparency in the monograph development and revision process. Users of the BP have benefitted from additional information on the interpretation and application of BP monographs; this is facilitated by a section on frequently asked questions. It is intended to update and expand this section in the future.

35. New documents have been added to provide additional guidance on the macroscopic and microscopic identification of the following Herbal Drugs: Berberis Aristata, Eclipta Prostrata Whole Plant and Withania Somnifera Root.

### Unlicensed Medicines

36. Monographs that only apply to unlicensed medicines are identified as such in the British Pharmacopoeia by the inclusion of a statement indicating that the medicines are not currently licensed in the United Kingdom.

37. The inclusion of BP monographs for unlicensed medicines has been widely recognised as a valuable addition to the publication since they provide legally enforceable standards for such products.

38. Information continues to be collected on widely used preparations for which there are currently no published standards. The BP continues to work with NHS groups and the pharmaceutical industry and receives appropriate advice on medicinal preparations prescribed in the UK for which no licensed formulations are

available. In addition to monographs for widely-used preparations, steps are being taken to identify other areas within the field of unlicensed medicines where the provision of information in the British Pharmacopoeia would be valuable.

**Traditional Herbal Medicines**

39. Information continues to be collected on a number of substances widely used in Traditional Chinese Medicine and in Ayurvedic Medicine in the UK for which there are currently no European standards. National and international collaboration is being sought to identify validated analytical methods and suitable standards.

**Homoeopathic Preparations**

40. The development of monographs for homoeopathic stocks and mother tinctures in order to support the simplified registration scheme for the licensing of homoeopathic preparations has been completed, other than for three new monographs where the work has been suspended pending receipt of samples.

**Liaison with Other Organisations**

41. The BP has been developing links with several universities. A number of laboratory-based projects have been identified with a view to developing suitable methods for inclusion in BP monographs. The purpose of these collaborations is to provide the students with real problems faced in the pharmaceutical industry and to update BP methods that are non-specific or require the use of harmful reagents. Lectures on the “Use of the British Pharmacopoeia” and “The Nomenclature of Medicines” have been given to pharmacy and chemistry students.

42. Work undertaken by a contract laboratory to develop and validate methods for Ivermectin Oral Solution was successfully completed during the year. The BP Laboratory subsequently carried out work to confirm the reproducibility of the methods and the resulting monograph was published in the British Pharmacopoeia (Veterinary) 2014.

43. A meeting between representatives from the Veterinary Medicines Directorate (VMD) and the BP took place in August. The purpose of the meeting was to progress discussions pertinent to the regulatory and quality requirements for veterinary medicines and how these affect the British Pharmacopoeia (Veterinary).

**BP Reference Materials**

44. 40 new BP Reference Materials were established to support the British Pharmacopoeia and British Pharmacopoeia (Veterinary) publications, 37 were replaced and 129 were re-tested to ascertain their continued stability.

45. The demand for these reference materials remained high throughout the year. 16853 vials were sold within the UK and to countries worldwide.

**Nomenclature**

46. The BP continued to provide advice and comments to the World Health Organization (WHO) Committee on International Nonproprietary Names (INN). Recommended INN (rINN) for products licensed in the UK are subsequently

adopted as British Approved Names. UK Experts attended two meetings during the year and contributed to the evaluation of INN requests and the development of WHO policies on drug nomenclature. Two rINN Lists (69 and 70) were published by WHO during the year.

47. The BP Secretariat is also responsible for assessing proposed invented names for medicines in the UK and providing the UK input to the EMA Naming Review Group. During the year over 600 proposed invented names were assessed on behalf of the MHRA and over 800 on behalf of the EMA.

**MHRA/NIBSC Merger**

48. The MHRA merged with the National Institute for Biological Standards and Control (NIBSC) on 1st April 2013. The newly expanded Medicines and Healthcare Products Regulatory Agency now consists of three centres: MHRA, NIBSC and the Clinical Practice Research Datalink (CPRD). The Secretariat has been working with colleagues from NIBSC in the areas of Herbal and Biological Medicines and it is anticipated that work in these areas will expand in the future.

49. A review of the future strategy of biologicals within the British Pharmacopoeia was undertaken during the year. Benefits from the merger were identified whereby additional expertise and knowledge can be applied and will assist in strengthening the pharmacopoeial control of biological and biotechnological products. The production by NIBSC of national biological reference preparations for the British Pharmacopoeia and the feasibility of developing monographs for biologicals at an earlier stage in the life cycle of a product, in particular those for biosimilars and monoclonal antibodies, are being explored.

50. A pilot study to work towards improving the authentication of herbs used for the practical evaluation of monographs for herbal and complementary medicines, focussing on the applicability of DNA bar-coding, was initiated. The practical work will start in early 2014 and will be evaluated after 12 months.

**150th Anniversary of the British Pharmacopoeia**

51. The first edition of the British Pharmacopoeia was published in 1864. The Secretariat has been working closely with colleagues in the Communications Division of the Medicines and Healthcare Products Regulatory Agency in order to develop a programme of events to celebrate the 150th anniversary of this publication in 2014.

52. Discussions are taking place with a view to re-branding the British Pharmacopoeia and the 2015 editions of the British Pharmacopoeia and British Pharmacopoeia (Veterinary), which will be published in August, will reflect the new brand.

53. A number of technical meetings will take place in London during April, including the annual meeting of National Pharmacopoeial Authority Secretaries and the Third International Meeting of World Pharmacopoeias. A conference on “The Quality of Medicines – Future Evolution” will also take place, which will provide an opportunity to celebrate the 150th anniversary.

## European Pharmacopoeia

54. The 8th Edition of the European Pharmacopoeia was published in July 2013 and came into effect on 1st January 2014. Supplements 8.1 and 8.2 to the 8th Edition were published in October 2013 and January 2014 respectively. Supplement 8.1 will come into effect on 1st April 2014 and Supplement 8.2 will come into effect on 1st July 2014. The text of these publications will be included in the next editions of the British Pharmacopoeia or British Pharmacopoeia (Veterinary), as appropriate.

55. The UK continued to play a highly active role in support of the work of the European Pharmacopoeia Commission and its expert groups, providing Chairs to three Groups of Experts and nine Working Parties and experts to all of the principal Expert Groups and Working Parties.

56. The BP Laboratory provides technical support for the work of the European Pharmacopoeia Commission. It participates in the voluntary scheme to validate draft monographs published in Pharmeuropa and provides technical data in support of the elaboration of new monographs and revision of existing monographs.

57. Supplementary lists of Approved Synonyms for names at the head of monographs of the European Pharmacopoeia were prepared and published on the recommendation of the British Pharmacopoeia Commission.

58. A list of the current membership of the United Kingdom delegation, and the names of the UK members of Groups of Experts and Working Parties during 2013, is included in **Appendix V**.

## International Liaison and Collaboration

59. Liaison was maintained on a wide range of topics relating to pharmacopoeial matters and nomenclature with various international organisations and authorities and other non-governmental bodies including the World Health Organization (WHO), the Australian Therapeutic Goods Administration Laboratories, the Canadian Health and Food Protection Branch, the United States Pharmacopeia (USP) and the United States Adopted Names (USAN) Council. This collaboration has been enhanced with the appointment of a number of overseas representatives to the Commission's Expert Advisory Groups and Panels of Experts.

60. BP Staff attended the Second International Meeting of World Pharmacopoeias which was organised by the World Health Organization and held in India. The meeting focussed on the development of guidelines on "Good Pharmacopoeial Practices" (GPP). Discussions on GPP will continue at the Third International meeting of World Pharmacopoeias, which will be held in London during 2014. During the year BP staff provided draft text for inclusion in the guidance document and submitted comments on sections prepared by the various drafting groups.

61. Throughout the year BP Secretariat staff have provided feedback to WHO on draft monographs for the International Pharmacopoeia, which has been greatly appreciated. Many of the standards included in the International Pharmacopoeia,

and the policies employed, are consistent with those in the British Pharmacopoeia.

62. The BP participated in the 48th Meeting of the WHO Expert Committee on Specifications for Pharmaceutical Preparations held in October 2013.

63. The BP attended the Third Global Summit of Pharmacopoeias, held in the USA. A number of issues were discussed, including the guidance on Good Pharmacopoeial Practices, the Global Pharmacopoeia Monograph Comparison Database and the USP spectral library database.

64. Representatives from the United States Pharmacopeia (USP) met with BP staff to discuss future collaboration, including the possibility of future informal collaboration work on the development of monographs for biological materials.

65. The project on informal prospective harmonisation with the USP has now expanded to include a number of new monographs and it is expected that a number of informally harmonised drug product monographs will be published in the British Pharmacopoeia 2015. The process has been further expanded to include the European Directorate for the Quality of Medicines & HealthCare (EDQM), thus enabling concurrent harmonisation discussions to occur between the BP, the USP and the EDQM for the drug substance and the corresponding drug products.

66. Along with representatives from the Medicines and Healthcare Products Regulatory Agency, the BP attended a meeting in China held between the MHRA, NIBSC, the Chinese Pharmacopoeia and the Chinese National Institute of Food and Drug Control. Discussion topics included four-way collaboration opportunities and areas of overlap.

67. Representatives from the Chinese Pharmacopoeia visited the BP during June to discuss BP monograph development and the establishment of BP reference materials.

68. During May a collaboration agreement was signed between the British Pharmacopoeia and the Ukrainian Scientific Pharmacopoeial Centre for the Quality of Medicines. This agreement allows BP monographs to be cited in the State Pharmacopoeia of the Ukraine.

69. As part of a wider meeting with the three centres of the Medicines and Healthcare Products Regulatory Agency, the BP met with representatives from the Scientific Centre on Expertise of Medical Application Products (SCEMAP) of the Ministry of Health of the Russian Federation. In addition to working with the BP, SCEMAP expressed an interest in collaborating with the agency in a number of areas including biologicals, biosimilars and the development of reference standards.

## ACKNOWLEDGEMENTS

70. The Commission wishes to record its immense gratitude to the staff of the British Pharmacopoeia and Laboratory Services Group of the Medicines and Healthcare Products Regulatory Agency concerned with the business of the Commission and its Expert Advisory Groups, Panels of Experts and Working Parties. Significant input to the work of the British Pharmacopoeia Commission continued to be

received from members of staff from the Licensing Division, the Vigilance & Risk Management of Medicines Division, the Inspection, Enforcement & Standards Division and the Information Centre of the Agency. In addition, members of staff of the Communications Division have worked closely with the BP Secretariat to prepare for the activities related to the celebrations for the 150th anniversary of the BP. Significant input has also been received from the BP and MHRA Laboratories, from the Department of Health, from the National Institute for Biological Standards and Control and from the Veterinary Medicines Directorate.

71. The Commission wishes to express its thanks to Mr V'Iain Fenton-May, who retired at the end of 2013 after a period of 16 years' service. Mr Fenton-May had been a member of the British Pharmacopoeia Commission since 1998 and its Vice-Chair since 2006. During the time the Commission was without a Chair he willingly took on the extra responsibilities required to enable the Commission to carry out its business in a timely manner. Commission was pleased to note that he would be continuing to serve as Chair of the Expert Advisory Group on Unlicensed Medicines, as Chair of one of the Medicinal Chemicals EAGs and as Chair of the Panel of Experts on Microbiology. Mr Fenton-May had also been a member of the UK delegation to the European Pharmacopoeia Commission from 2006 to 2013. He would be remaining as the Chair of the Ph Eur Working Party on Pharmaceutical Preparations and had been appointed as Chair of the Ph Eur Expert Group on Biological Methods and Statistical Analysis with effect from 1st January 2014. The Commission would like to place on record its thanks to Mr Fenton-May for his long-standing support of the work of both the British and European Pharmacopoeias.

72. The Commission wishes to express its gratitude to all Expert Advisory Group, Panel and Working Party members for the invaluable contribution they have made towards the continuing improvement of standards in the British Pharmacopoeia and to members of the United Kingdom delegation to the European Pharmacopoeia Commission and to UK members of its Groups of Experts and Working Parties who have unstintingly provided time, attention and expertise to the work of that Commission.

73. The Commission wishes to acknowledge the advice of the publishing team at The Stationery Office in the production of the British Pharmacopoeia 2014 and the British Pharmacopoeia (Veterinary) 2014.

74. The Commission also wishes to acknowledge the staff at the Medicinal Plant Names Services at the Royal Botanical Gardens, Kew, who provided advice on the Latin scientific names cited in the new national monographs for Traditional Herbal Medicines.

## AWARDS

75. The Commission was pleased to note that Dr Lincoln Tsang had been awarded the Client Choice International Award for 2013 in the Life Sciences and Healthcare category and that Ms Christine Leon, a member of the Expert Advisory Group on Herbal and Complementary Medicines, had been awarded an MBE for services to the UK China Science Relationship.

## OBITUARIES

76. It was with sadness and regret that the Commission learnt of the deaths of Professor Geoff Phillips and Dr Brian Wills. Professor Phillips had been a former member of the British Pharmacopoeia Commission and had served as Chair of the former Committees on General Chemicals and Nomenclature. Dr Wills had also been a former member of the BP Commission and had served as the Chair of the former Pharmacy Committee.

# MEMBERSHIP OF THE BRITISH PHARMACOPOEIA COMMISSION

## Chair

**Professor Kevin M G Taylor**[1] BPharm PhD FRPharmS
Professor of Clinical Pharmaceutics, UCL School of Pharmacy

## Members

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

**Mr Barry Capon** CBE MA DL
Lay Representative. Non-executive Director, Norfolk and Suffolk NHS Foundation Trust

**Dr Graham D Cook** BPharm PhD MRPharmS
Senior Director, Process Knowledge/Quality by Design, Pfizer

**Mr Andrew Coulson** BVetMed MSc MRCVS
Member of the Royal College of Veterinary Surgeons; former Superintending Inspector, Science & Research Group, The Home Office

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

**Mr V'lain Fenton-May**[2] BPharm MIPharmM FRPharmS **(Vice-Chair)**
Former Specialist Quality Controller to the Welsh Hospitals

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

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

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

**Dr Gerard Lee** BPharm PhD FRPharmS MRSC CChem
Former Group Manager: British Pharmacopoeia and Laboratory Services, MHRA; former Secretary & Scientific Director, British Pharmacopoeia Commission

**Dr Brian R Matthews** BPharm PhD FRPharmS FTOPRA MRI
Consultant on pharmaceutical and medical device regulatory affairs; former Senior Director, EC Registration, Alcon Laboratories

**Professor John Miller** MSc PhD MRSC CChem
Visiting Professor, Strathclyde Institute of Pharmacy and Biomedical Sciences; former Head of the EDQM Laboratory

**Dr Ronald Torano** BSc PhD MRSC CChem
Pharmacopoeial Intelligence and Advisory Specialist; GlaxoSmithKline

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

**Mrs Josephine Turnbull** LLB
Lay Representative. Chair of Tees, Esk and Wear Valley NHS Foundation Trust

**Dr Paul Varley** BSc PhD
Vice President of Biopharmaceutical Development, Medimmune Limited

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

**Secretary and Scientific Director**

**Dr Samantha Atkinson** BSc MSc PhD MRSC; Visiting Fellow, Reading University
Group Manager, BP & Laboratory Services, MHRA

[1] 1st October 2013 to 30th September 2017
[2] Retired, 31st December 2013

# MEMBERSHIP OF EXPERT ADVISORY GROUPS, PANELS OF EXPERTS AND WORKING PARTIES OF THE BRITISH PHARMACOPOEIA COMMISSION

## EXPERT ADVISORY GROUPS

| | |
|---|---|
| ABS: Antibiotics | R L Horder (**Chair**), G D Cook (**Vice-Chair**), P Ellis, V Jaitely, P Jones[1], A Livingstone, W Mann, J Miller, N Thomas, B White, I R Williams |
| BIO: Biological and Biotechnological Products | L Tsang (**Chair**), M A Dow[1] (**Vice-Chair**, *until March*), P Varley (**Vice-Chair**, *from September*), A F Bristow, D H Calam, J Cook, L Findlay, S Gill, E Griffiths, A O Onadipe, B Patel, A M Pickett, T Pronce, I Rees, D Sesardic, P Sheppard, W J Tarbit, J N A Tettey, A H Thomas, R Thorpe |
| HCM: Herbal and Complementary Medicines | E Williamson (**Chair**), L A Anderson (**Vice-Chair**), T Chapman, A Charvill, K Helliwell, P Hylands, C Leon, A C Moffat, M Pires, M Rowan, K Strohfeldt-Venables, J Sumal, P Viner, C Wright, K Zhao (*Corresponding members* SS Handa, A Krauss, Z-T Wang) |
| MC1: Medicinal Chemicals | A G Davidson (**Chair**), D Cairns (**Vice-Chair**), M Ahmed, J C Berridge, M Broughton, A J Caws, P Fleming, V Loh, W J Lough, D J Malpas, G Marco[1] |
| MC2: Medicinal Chemicals | G Cook (**Chair**), C T Goddard (**Vice-Chair**), M Cole, A Gibson, S Jones[1], M A Lee[1], J Lim, J Miller, P Murray, J Qiu, A Ruggiero, M Turgoose (*Corresponding members* M Brits, W Sherwin) |
| MC3: Medicinal Chemicals | V Fenton-May (**Chair**), E Williamson (**Vice-Chair**), M Almond, S Arkle, C T Goddard, P Hampshire, W K L Pugh, B Rackstraw, R Torano, M Tubby, I R Williams |
| NOM: Nomenclature | J K Aronson (**Chair**), L Tsang (**Vice-Chair**), M Ahmed, S Clarke, D Mehta, G P Moss, R Thorpe (*Corresponding members* R G Balocco Mattavelli, E M Cortés Montejano, A D McNaught, J S Robertson) |
| PCY: Pharmacy | R L Horder (**Chair**), B R Matthews (**Vice-Chair**), M Aulton, E Baker, N Broad, G Buckton[1], G Davison, G Eccleston, D Elder, R A Lowe, J MacDonald, J F McGuire, S C Nichols[1] |
| ULM: Unlicensed Medicines | V Fenton-May (**Chair**), M G Lee (**Vice-Chair**), S Branch, A Charvill, W Goddard, S Jones, M A Oldcorne, N J Precious, J Rothwell, M Santillo, J Smith, P Weir |

## PANELS OF EXPERTS

| | |
|---|---|
| BLP: Blood Products | K Chidwick, A R Hubbard, S Jenkins[1], P Varley |
| IGC: Inorganic and General Chemicals | C T Goddard (**Chair**), M Almond, A C Cartwright, P Henrys, D Malpas, C Mroz, D Riches |
| MIC: Microbiology | V Fenton-May (**Chair**), S Denyer, D P Hargreaves, B R Matthews, P Newby |
| RAD: Radioactive Materials | J Ballinger, J Brain, D Graham, S R Hesslewood, G Inwards, P Maltby, A M Millar[1], R D Pickett, R Smith, S Waters |
| VET: Veterinary Medicines | E Williamson (**Chair**), P Lees (**Vice-Chair**), A Cairns, S Cockbill, A Coulson, D Evans, E Flahive, B Ward |
| VIP: Veterinary Immunological Products | A-M Brady, K Redhead, J Salt, P W Wells |

## WORKING PARTIES

| | |
|---|---|
| CX: Excipients | G Buckton[1] (**Chair**), C Mroz (**Vice-Chair**), E Anno, R Cawthorne, B R Matthews, M I Robertson, K Slevin |

[1] Resigned during the year

# MEMBERS OF THE BRITISH PHARMACOPOEIA COMMISSION STAFF

## SECRETARY AND SCIENTIFIC DIRECTOR

Dr S Atkinson

## SECRETARIAT

Mrs M Vallender (*Editor-in-Chief)*
Mr S Young (*Head of Analytical Science*)
Mrs M Barrett
Ms H Corns
Mr P Crowley (*from March*)
Mr A Evans
Ms J Francomb
Mr A Gibb
Dr P Holland
Dr R A Pask-Hughes
Ms C Pitt (*from March*)
Mr J Pound
Dr F J Swanson
Mr M Whaley

## LABORATORY MANAGEMENT BOARD

Dr S Atkinson (*Secretary and Scientific Director*, BP)
Mrs M Vallender (*Editor-in-Chief,* BP)
Mr S Young (*Head of Analytical Science*, BP)
Dr K Courtney (*BP Laboratory Team Leader*, LGC)
Dr D Craston (*The Government Chemist; Director, Research & Technology*, LGC)
Mr D Holcombe (*MHRA Laboratory Manager,* LGC)
Mr S Wood (*Head of Regulatory and Legislative Service*s, LGC)

## ADMINISTRATIVE

Mrs M Cumberbatch (*until June*)
Mr B Delahunty
Ms H Jagpal (*from June*)
Mr W Jeffries
Ms D Myburgh (*until September*)
Miss J Paine
Ms N Salmon

## BRITISH PHARMACOPOEIA COMMISSION PUBLICATIONS

Publications may be purchased from TSO Publications Centre, from Government Bookshops or from the Pharmaceutical Press.

**British Pharmacopoeia 2014 package**

Consisting of:-

British Pharmacopoeia 2014

British Pharmacopoeia (Veterinary) 2014

CD-ROM / Online Access (single-user licence, allowing access to three in-year electronic updates)

*(Subscription price £1000; £875 for print and online versions only)*

**Individual BP Monograph (only supplied electronically)**

*(Price £200 for the first text, £150 each for the second and third texts)*

**British Approved Names**

British Approved Names 2012: Supplement No. 2

*(Price £20)*

## EUROPEAN PHARMACOPOEIA COMMISSION

**UNITED KINGDOM DELEGATION DURING 2013:** S Atkinson,
V Fenton-May

Alternates: A G Davidson,
R L Horder,
M Vallender

## MEMBERS OF GROUPS OF EXPERTS FROM THE UNITED KINGDOM DURING 2013:

| | | |
|---|---|---|
| Group 1 | Biological Methods and Statistical Analysis | V Fenton-May |
| Group 6 | Biological Substances | A F Bristow |
| Group 6B | Human Blood and Blood Products | A R Hubbard |
| Group 7 | Antibiotics | B White |
| Group 9G | Medicinal Gases | M G Lee (*Chair*), P Henrys |
| Group 10A | Organic Chemistry (Synthetic Products) | D J Malpas |
| Group 10B | Organic Chemistry (Synthetic Products) | S Arkle |
| Group 10C | Organic Chemistry (Synthetic Products) | A J Caws |
| Group 10D | Organic Chemistry (Synthetic Products) | C T Goddard |
| Group 11 | Organic Chemistry (Natural Products) | A G Davidson (*Chair*), M Tubby |
| Group 12 | Dosage Forms and Methods | R Horder |
| Group 13A | Phytochemistry A | K Helliwell |
| Group 13B | Phytochemistry B | K Helliwell (*Chair*) |
| Group 13H | Fatty Oils and Derivatives | R Cawthorne, M Evans (*Specialist*) |
| Group 14 | Radioactive Compounds | R D Pickett |
| Group 15 | Sera and Vaccines | D Sesardic, S Schepelmann (*Specialist*) |
| Group 15V | Veterinary Sera and Vaccines | A-M Brady |
| Group 16 | Plastic Containers for Pharmaceutical Use | K Allen |
| Group P4 | Procedure 4 | S Young |

## MEMBERS OF WORKING PARTIES FROM THE UNITED KINGDOM DURING 2013:

| | |
|---|---|
| Alkyl Mesilates | J Midgley (*Chair*) |
| Allergens | A Cook |
| Bacterial Endotoxins Test | L Findlay |
| Botulinum Toxin | D Sesardic |
| Carbohydrates | J Michaud (*Chair*) |
| Cell Therapy Products | M O'Kane |
| Chromatographic Separation Techniques | S Young |
| Chairs of Chemical Groups | A G Davidson, M G Lee |
| Dialysis Solutions | M G Lee (*Chair*) |
| Extracts | K Helliwell (*Chair*), L Anderson, M Pires |
| Finished Product Monographs (Pilot Phase) | S Atkinson |
| Functionality-related Characteristics | C Mroz |
| Gene Therapy Products | E Pollitt |
| Glycan Mapping | C T Yuen |
| Heavy Metals | A Evans |
| Homoeopathic Manufacturing Methods | R A Pask-Hughes, J Sumal |
| Homoeopathic Raw Materials and Stocks | R A Pask-Hughes, J Sumal |
| Host-cell Proteins | A Kippen |
| Inhalanda | S C Nichols |
| Inorganic and Organic Chemistry | C T Goddard |
| Microbiological Quality of Herbal Drugs | K Helliwell (*Chair*) |
| Modern Microbiological Methods | S Denyer, G Marco |
| Monoclonal Antibodies | R Thorpe (*Chair*), P Varley |
| Monocyte Activation Test | L Findlay |
| Mycoplasmas | R A J Nicholas |
| Nuclear Magnetic Resonance Spectroscopy | C Jones |

| | |
|---|---|
| Pharmaceutical Preparations | V Fenton-May (*Chair*), M G Lee |
| Precursors for Radiopharmaceutical Preparations | J Brain |
| Procedure 4 for Biologicals | K Chidwick |
| Process Analytical Technology | N Broad, I Lynch |
| Production and Compounding of Radiopharmaceutical Preparations | P Maltby |
| Raw Materials for the Preparation of Cellular and Gene Therapy Products | L Bisset |
| Rules of Procedure | M G Lee |
| Special Revision Programme | M G Lee |
| Standard Terms | M Ahmed |
| Statistics | R Gaines Das |
| Traditional Chinese Medicines | M Whaley |
| Vibrational Spectroscopy and Analytical Data Modelling | N Broad |
| Water for Pharmaceutical Use | M G Lee (*Chair*), A Hopkins |
| Water for the Preparation of Extracts | K Helliwell (*Chair*) |

# CODE OF PRACTICE FOR CHAIRMEN AND MEMBERS OF THE COMMISSION ON HUMAN MEDICINES, CERTAIN COMMITTEES AND EXPERT ADVISORY GROUPS

## 1. INTRODUCTION

### Purpose of the Code

1.1 This Code of Practice sets out the rules to be followed by chairmen and members of advisory committees holding and declaring interests in the pharmaceutical industry. The Code of Practice also provides guidance on holding and declaring other relevant interests, and on how interests that have been declared will be managed. The Code applies to chairmen and members of all the statutory committees and Expert Advisory Groups (EAGs) established to contribute advice to the Licensing Authority on the regulation of medicines available on the UK market. Separate rules apply to the British Pharmacopoeia Commission (BPC) because of their different role and remit.

### Importance of impartiality

1.2 Ministers expect the advice they receive on matters relating to the regulation of medicines to be impartial. Ministers also expect to be able to seek such advice from a wide range of highly skilled professionals who are senior and well regarded in their respective fields. Many experts in the field of medicines have, or have had, connections with the pharmaceutical industry and other commercial organisations whose business may be considered relevant to their work on the advisory bodies but may have an impact on their impartiality. For example, the University department for which an individual is responsible may have received a research grant from industry, or the individual may have shareholdings from previous industry employment.

1.3 To reassure Ministers and the public that the advice on which decisions about medicines is based is impartial, it is important to have in place a robust policy governing the declaration and management of relevant interests. In the interests of transparency and accountability, this Code of Practice, the declarations made by chairmen and members of the various committees, and the actions taken to manage potential conflicts of interest are made public. In addition, where an individual has declared in advance of a meeting an interest that would exclude him or her from the relevant discussions, this information will be used by the secretariat to ensure that, wherever possible, the relevant committee papers are not sent to that individual.

## 2. SCOPE

### Committees and groups to which this Code applies

2.1 The Code of Practice applies to the chairmen and members of the following committees and groups:

- Commission on Human Medicines (CHM)
- The following committees ("the Committees"):

  Herbal Medicines Advisory Committee (HMAC);

  The Advisory Board on the Registration of Homeopathic Products (ABRHP)

- The Expert Advisory Groups (EAGs) established by the CHM and/or the Committees.

2.2 This Code of Practice does not apply to the British Pharmacopoeia Commission (BPC), which does not advise Ministers directly. A separate Code has been developed for the BPC to take account of their different role and remit.

## 3. DEFINITIONS

3.1 For the purposes of this Code of Practice, the following definitions apply:

### Pharmaceutical Industry

3.2 "Pharmaceutical industry" means:

- Companies, partnerships or individuals who are involved with the manufacture, sale or supply of medicinal products, including herbal medicinal products and homeopathic products;
- Trade associations representing companies involved with such products;
- Companies, partnerships or individuals who are directly concerned with research, development or marketing of a medicinal product, including herbal medicinal products and homeopathic products which is being considered by the CHM or by one of the Committees or Expert Advisory Groups.

References to "the pharmaceutical industry" include cases involving a single company.

### Immediate family

3.3 "Immediate family" means:

Spouse or partner and members of the family living in the same household. Members of the family include dependent children, any adult children or other relative (such as parent) living in the same household.

## 4. INTERESTS WHICH NEED TO BE DECLARED

### Summary of interests that need to be declared

4.1 It is the responsibility of each individual to identify and to declare all relevant interests. The following types of interest must be declared by chairmen and members of all committees and groups:

- Their own financial interests in the pharmaceutical industry; (financial interests are either personal or non-personal, and either specific to the product being discussed, or non-specific);
- Financial interests in the pharmaceutical industry held by members of their immediate family;
- Any other matter that could affect their impartiality, or that could reasonably be perceived as affecting their impartiality. Some examples of interests that are relevant in the context of this Code of Practice, not all associated with the pharmaceutical industry, are set out in section 4.7 below.

4.2 The following paragraphs describe in more detail the types of interests that must be declared. The procedures for handling interests that have been declared are described in Section 7.

### Personal interests

4.3 A personal interest in the context of this Code, involves the payment, in any form, to an individual personally, by a pharmaceutical company whose business may be directly affected by the advice of the advisory body. At a meeting, personal interests must be declared as ***specific*** (that is, payment relates to a particular product under consideration), or as ***non-specific*** (that is, not related to the particular product under discussion). The following main examples of interests to be declared should not be regarded as a definitive list, and the Medicines and Healthcare products Regulatory Agency (MHRA) secretariat to each committee will advise if a chairman or member is in any doubt.

***Consultancies:*** any consultancy, directorship, position in or work for the pharmaceutical industry which attracts regular or occasional payments in cash or kind;

***Fee-paid work:*** any work commissioned by the pharmaceutical industry for which the individual is paid in cash or kind;

***Shareholdings:*** any shareholding in or other beneficial interest in the pharmaceutical industry. This does not include shareholdings through unit trusts or similar arrangements where the individual has no influence on financial management;

***Expenses/hospitality provided by a pharmaceutical company:*** special rules apply to attendance at conferences or similar events. These are covered in paragraphs 4.8 et seq. below;

***Unit trusts and similar:*** Assets over which chairmen and members and/or their immediate family have no financial control (such as holdings in a wide share portfolio -Unit Trust or similar - where the Fund Manager has full discretion over the composition of the portfolio) do not need to be declared. However, funds held in a portfolio in which chairmen and members and/or their immediate family have the ability to instruct the Fund Manager as to the composition of the fund must be declared.

***Pension entitlement:*** Accrued pension rights from earlier employment in the pharmaceutical industry do not need to be declared.

**Personal interests - special rules applicable to the CHM and the Committees**

4.4 The chairman and members of the CHM, HMAC and ABRHP serve on the committees that provide advice direct to the Licensing Authority. For this reason, they are not permitted to hold any current personal interests in the pharmaceutical industry. This policy also applies to the chairmen of the Pharmacy and Standards EAG, the Pharmacovigilance EAG and the Biologicals and Vaccines EAG by virtue of their membership of the CHM. The chairmen and members of the CHM and the chairmen and members of the HMAC and ABRHP, and the chairmen of the three EAGs specified are required to make a declaration on appointment that they are disposing /have disposed of any such current personal interests.

4.5 The chairmen and members of these committees have three months from the date of appointment to dispose of any current personal interests in the pharmaceutical industry. During this period, they are required to declare any relevant current personal interests at meetings and to exclude themselves from discussion on the relevant product(s) and abstain from any vote.

**Non-Personal Interests**

4.6 A non-personal interest in the context of this Code, involves payment that benefits a department for which an individual is responsible, but is not received by the member personally. As with personal interests, non-personal interests at a meeting must be ***specific*** or ***non-specific***. The main examples that follow should not be regarded as a definitive list, and the advice of the committee secretariat provided by the MHRA should be sought if a chairman or member is in any doubt.

***Fellowships:*** the holding of a fellowship endowed by the pharmaceutical industry or any other relevant industry;

***Support by the pharmaceutical industry or any other relevant industry:*** any payment, other support or sponsorship by the pharmaceutical or other industry that does not convey any pecuniary or material benefit to the individual personally but that benefits his/her position or department;

***Grants from a company:*** for example, for the running of a unit or department for which an individual is responsible;

***Grants or fellowships to sponsor a post or staff member in the unit for which the individual is responsible:*** this does not include financial assistance given to individual students;

***Commissioning of research or other work or advice from staff who work in a unit for which the individual is responsible.***

**Other relevant interests**

4.7 It is not only financial interests in the pharmaceutical industry that are relevant. A wide range of other matters may also be considered to be relevant, depending on the circumstances and matters under consideration by a committee on which an individual serves, and could include non-financial interests. There are no hard and fast rules concerning "other" interests that need to be declared. In considering whether an interest is relevant and therefore should be declared, the guiding principle must be whether the matter might reasonably be perceived as affecting a member's impartiality. Some examples of matters that might fall under this heading are set out below. These are not exhaustive and individuals should always seek advice from the MHRA Secretariat if they are in any doubt about whether or not a matter is relevant:

- An individual, or his department, has done research work relating to a particular product, or class of products. Although the research has not been funded by any particular pharmaceutical company, the research has taken a particular line e.g. in relation to the safety of the products, or their efficacy;

- An individual has made public statements (either favourable or unfavourable) about a particular company, or product, or class of products or about a competitor's product or class of product;

- The relevant committee is considering whether a product should be reclassified e.g. from prescription only, to a pharmacy medicine, and the individual has a particular interest in the reclassification being made e.g. because he is a retail pharmacist and he will benefit financially;

- An individual participates in, or is connected with, a charity or pressure group that would have an interest in the outcome of the advice being given;

- An individual has a family member who suffers from an illness who would benefit from treatment if a product under discussion were to be authorised;

- An individual has a family member who has suffered a severe reaction or other problem as a result of treatment with a product under discussion;

- Matters relating to persons who are not immediately family members, but are closely connected with the committee expert e.g. adult child no longer living in the same household, or non-family member whose work or other interests are closely associated with the pharmaceutical industry and which could reasonably be perceived as affecting the individual's impartiality. An example might be where a committee is giving advice in

relation to a product and a close family member or friend has had a major development responsibility for that product;

- Interests in a company manufacturing the delivery system (e.g. syringes or other medical equipment) for a particular medicinal product.

**Attendance at conferences, scientific meetings and similar**

4.8 Government recognises that it is usual for conferences, scientific meetings and other events associated with healthcare, medicines or related matters to receive some form of sponsorship either directly, or indirectly via a special fund, from the pharmaceutical industry. Government also recognises the importance of being able to receive advice from leading experts who are able to keep themselves up to date with developments at the cutting edge of science, and that this is mainly done through attendance at educational and scientific events and meetings. It is therefore essential to set out rules for attendance at these and similar events as questions may be legitimately raised as to whether participation in the event, or even mere attendance, will compromise their impartiality in any way. This is particularly important in respect of chairmen and members of the CHM, HMAC and ABRHP (including the chairmen of the Pharmacy and Standards EAG, the Pharmacovigilance EAG and the Biologicals and Vaccines EAG) who, as set out above, are not permitted to hold personal interests in the pharmaceutical industry.

4.9 The nature of the events that fall within the scope of this Code of Practice and the industry sponsorship received can vary widely from, at one extreme, a conference sponsored by a single company to launch a product to, at the other extreme, a scientific meeting organised by a learned society that has received some financial support from a number of companies paid into a dedicated meeting fund. Between these extremes there are many variations in events and funding that may occur.

4.10 In order that the chairmen and members of CHM, HMAC, ABRHP and the three EAG chairmen specified in paragraph 4.8 above, should be able to attend appropriate scientific events to keep their knowledge up to date, the MHRA has established a discretionary fund to meet the reasonable expenses (e.g. travel and accommodation costs) incurred in their attendance. The relevant MHRA committee secretariat will administer the fund, and chairmen and members wishing to claim the costs of attendance at such events must make an application in good time to enable appropriate travel and other arrangements to be made. The fund will cover educational events that are relevant to maintaining the expertise of individuals serving on the CHM, HMAC, ABRHP and the three specified EAGs, where acceptance of financial support from industry (for example a single pharmaceutical company) would not be appropriate. Separate guidance on the allocation of resources from the fund has been developed for use by the MHRA secretariat.

4.11 In some cases it will permissible for members of CHM, HMAC, ABRHP and these three EAG chairmen to attend events sponsored by the pharmaceutical industry (and accept the payment of their expenses) without recourse to the MHRA discretionary fund. For example, where a learned society holds an international conference that is sponsored by a number of different pharmaceutical companies, it will generally be acceptable for the member to accept such an

invitation and to receive payment of expenses, although in such instances declaration of attendance and receipt of funding must be declared in the normal way.

4.12 If funding and/or expenses are paid specifically for an individual's attendance but nevertheless paid to his department rather than the individual himself, it will not normally be acceptable for the individual to attend.

4.13 Benefits of this nature paid to an immediate family member that also benefit the committee chairman or member (e.g. a company pays his or her flight costs so that the he or she can attend a conference with a family member) must be declared as the individual's own interest. However, there is no requirement to declare educational conferences and similar events attended by immediate family members.

4.14 If an individual attends an educational conference or similar, he or she should avoid participation in, for example, "satellite" meetings sponsored and arranged by specific companies or focusing on specific products where involvement in discussions might reasonably be perceived as affecting his or her impartiality. If in doubt, this must be raised with the MHRA Secretariat at the earliest possible opportunity, who will be able to provide further guidance.

4.15 The rules for holding personal interest in the pharmaceutical industry do not apply to chairmen and members of EAGs, apart from chairmen of the 3 EAGS described at paragraph 4.8 above, and for the reasons set out in paragraph 4.4 above. Therefore, these experts may attend meetings sponsored by the pharmaceutical industry and accept funding of expenses, but these must be declared.

4.16 Attendance at conferences, scientific meetings and other events relevant to this Code must be declared at the first meeting of the committee after the event has taken place. This declaration may affect an individual's participation in discussions over the subsequent months. The declarations will be published annually in the report of the work of the committees.

4.17 The situations described are not exhaustive and individuals should always seek advice from the MHRA Secretariat if they are in any doubt about whether or not they should attend, or whether, having attended, they need to declare attendance as an interest.

## 5. SPECIAL POSITION OF EXPERTS ATTENDING FOR THE DAY AND EXPERTS CALLED TO ADVISE THE COMMITTEES ON SPECIFIC ISSUES

5.1 Experts who are invited to attend committees for the day, for example if a regular member cannot be available or cannot participate in discussions because of his or her interests, are known as "Experts for the Day". They are co-opted as full members of the committee for that day, may participate fully in all discussions and may vote. They are therefore required to make a full declaration of interests in the same way as is required of a full member of that committee. Experts called

to advise a committee on particular issues may not hold interests in the issue under discussion.

## 6. DECLARATION OF INTERESTS

6.1 Chairmen and members are required to make a full declaration of interests on appointment and annually. They must also inform the MHRA secretariat promptly of any changes or updates to the terms of their declaration during the year. This includes reporting promptly attendance at events described in paragraphs 4.8 – 4.17. If an individual is uncertain as to whether or not an interest should be declared, he or she must seek guidance from the MHRA secretariat. Chairmen and members are also required to make further declarations of relevant interests at meetings when they will be advised as to the procedure that will apply.

### Annual declaration

6.2 The annual declaration must include all the financial (personal and non-personal) interests in the pharmaceutical industry of the chairmen and members currently held or held in the last 12 months and financial interests in the pharmaceutical industry that they know of that are held by their immediate family. Members and chairmen are also required to include in the annual declaration details of any other matter which could reasonably be regarded as affecting their impartiality.

6.3 The declaration of certain interests will not be restricted to the last 12 months. For example, an individual's significant involvement in the development of a particular product will need to be declared each year as well as at relevant meetings, and may restrict that individual's participation in some discussions.

6.4 The chairmen and members' declaration of their own interests will identify them with the interests declared, but the interests declared do not need to be quantified. For example, in declaring a grant received by a department for which the individual is responsible, only the company name is required, not the value of the grant.

6.5 When the annual declaration includes matters relating to other persons, names are not required, nor do the interests declared need to be quantified. For example, in declaring shareholdings only the company name is required, not the numbers or values of shares held. Family members should be referred to simply as: "immediate family member" and closely connected persons as "other person". In nearly all circumstances this will protect the anonymity of those whose interests must be declared by the serving committee member, although we recognise that in very exceptional circumstances it may be possible for that individual to be identified.

6.6 The annual declaration made by all chairmen and members of all the CHM, the Committees and EAGs will be published each year in the Annual Report of the Advisory Bodies.

**Declarations at Meetings**

6.7 Chairmen and members are required to declare relevant interests at meetings, whether or not those interests have previously been declared to MHRA. The type of interest must be declared, that is, whether it is personal or non-personal, specific or non-specific or other.

6.8 If an issue arises for discussion and an individual is concerned about a matter that could be regarded as affecting his or her impartiality and this matter has not already been declared, he or she must raise this with the MHRA secretariat in advance of the meeting if possible. This will enable the secretariat, wherever possible, to ensure that he or she is not sent any papers concerning issues on which the individual cannot be regarded as impartial. Where it has not been possible to identify such issues in advance, the individual must raise the issue with the MHRA secretariat or the chairman as early as possible before the meeting takes place, and in any event before discussion of the relevant agenda item. The chairman of the committee is responsible for taking the decision on how declared interests should be handled.

## 7. PARTICIPATION IN DISCUSSIONS WHEN AN INTEREST HAS BEEN DECLARED

7.1 "Taking part in discussions" means speaking at meetings or voting. Where an individual is not to take part in a discussion, he or she should leave the room before the discussion commences, and return only when that agenda item is complete.

7.2 The following paragraphs describe, for each category of interests declared, the actions to be taken.

**Personal Interests**

7.3 A ***personal specific interest*** will have been declared if an individual has worked on the product under consideration and is receiving or has received payment for that work. As a general rule, the individual will normally not be allowed to take part in discussions as they relate to that product, except where the Chairman exercises his discretion (which will be rarely exercised) to answer questions from other members. A significant involvement in the development of a product will usually debar an individual from ever participating in discussion on that product. A less significant involvement, or less specific work with or on a product, may not permanently debar an individual, but such decisions will need to be taken on a case by case basis, taking account of the nature of the involvement, its specificity and when the work was undertaken.

7.4 If an individual has declared a ***personal non-specific interest*** the individual must take no part in discussions on that agenda item, except at the Chairman's discretion to answer questions from other members. If the personal non-specific interest relates to shares that have been disposed of, the individual will generally be permitted to take part in discussions once three months have elapsed from the date of the disposal of them If the personal non-specific interest relates to other matters, such as a payment received from a pharmaceutical company, the individual will generally be permitted to take part in discussions once 12 months has elapsed from the date of receipt of payment. However, in some cases it will

not be appropriate for the individual to take part even though 12 months have elapsed – for example, where he has an ongoing consultancy or other financial relationship with the pharmaceutical company.

7.5 If the individual has declared a personal interest in relation to a member of his or her immediate family, he or she should similarly take no part in discussions except at the Chairman's discretion to answer questions from other members. Such interests may range from a family member's major role in the development of a product under consideration to a family member's shareholdings.

**Non-Personal Interests**

7.6 *A **non-personal specific interest*** will have been declared if the department for which the individual is responsible is currently receiving payment in respect of work done on the product. The individual will generally not be able to take part in proceedings where a department for which he has responsibility has carried out specific work on the product under discussion.

7.7 A ***non-personal, non-specific interest*** will not normally debar an individual from taking part in discussions, unless exceptional circumstances arise in which it is not appropriate for them to do so.

7.8 If an individual declares non-personal interests of an immediate family member, this will not generally prevent him or her from taking part in discussions.

**Other Interests**

7.9 If an individual has declared an interest which does not fall within one of the categories described, but which he or she considers could be perceived as affecting his or her impartiality, whether that individual will be permitted to take part in discussions will depend upon the circumstances. In some cases, it will be sufficient for the individual to declare the interest, so that others taking part in the discussion are aware of his or her interests and can view his or her contribution in that light. An example might be where a member owns retail pharmacies and the discussion addresses the classification of a product from prescription to non-prescription status. In other circumstances it may not be appropriate for an individual to take any part in discussions, except at the chairman's discretion to answer questions from other members. The chairman and/or the MHRA Secretariat will advise on these matters. The chairman of the committee is responsible for taking the decision on how declared interests should be handled.

**Rival Products**

7.10 It is important to remember that not only the company whose application is being considered will be affected by the advice that is given by advisory bodies – companies who make competitor products may also be affected.

7.11 If a product is being discussed and an individual is aware that he or she has an interest in a company which markets a rival product, the business of which will directly benefit or suffer as a result of the advice that is given, the individual must declare that interest at the meeting. An example might be where an application for a generic product is being considered and the individual holds an interest in the current brand-leader, or where a new active substance is under consideration

that will directly affect the market of another company for a similar product in which an individual has an interest. Whether the individual will be permitted to take part in discussions will depend upon the circumstances and the extent to which the business of the competitor is likely to be affected

7.12 There is no requirement to carry out specific research to identify issues such as these – individuals need only to declare interests of which they are aware.

**Consideration of Classes of Products**

7.13 If an advisory body is considering issues relating to a class of products, the issue of interests remains relevant. Individuals must still declare interests in the usual way. Whether they will be permitted to take part in discussions will depend upon the circumstances, including the class of products being considered, the nature of the advice being given.

## 8. RECORD OF INTERESTS

8.1 A record is kept in the MHRA of:

- names of chairmen and members who have declared interests on appointment, when an interest first arises or through the annual declaration, and the nature of the interest;

- names of chairmen and members who have declared interests at meetings of the CHM, the Committees and EAGs, giving dates, names of relevant products and companies, details of the interest declared and whether the individual took part in the proceedings.

## 9. PUBLICATION

9.1 Interests declared to the MHRA by chairmen and members of all committees, including EAGs, will be published each year in the Annual Reports of the CHM and the Committees (normally published in July).

9.2 Interests of immediate family and other closely connected people declared by chairmen and members will be included in the Annual Reports. This information will provide only the name of the committee chairman or member, the source of the interest (e.g. the company name), will not provide any financial information nor numbers (e.g. for shares) nor identify the family member or other holding the interest by name.