# Advisory Board on the Registration of Homeopathic Products

# Herbal Medicines Advisory Committee

## Annual Reports 2017

**Medicines & Healthcare products Regulatory Agency**

**Medicines & Healthcare products Regulatory Agency**

# Advisory Board on the Registration of Homeopathic Products

# Herbal Medicines Advisory Committee

## Annual Reports 2017

# LIST OF CONTENTS

# FOREWORD BY SIR MICHAEL RAWLINS, CHAIRMAN OF THE MEDICINES AND HEALTHCARE PRODUCTS REGULATORY AGENCY

I am pleased to present the Annual Reports of the Advisory Board for the Regulation of Homeopathic Products and the Herbal Medicines Advisory Committee, along with a record of Members' interests in the pharmaceutical industry and code of practice.

Importantly, the work of our Expert committees continues to meet the highest standards. I would like to thank the Chair and Members whose professional expertise, commitment and hard work, play a vital role to ensure the medicines we take continue to be safe.

**Sir Michael Rawlins**
**Chairman of the MHRA**

# ADVISORY BOARD ON THE REGISTRATION OF HOMEOPATHIC PRODUCTS ANNUAL REPORT 2017

## INTRODUCTION

1. The Advisory Board on the Registration of Homeopathic Products ('the Board') was established in 1994 by the Medicines (Advisory Board on the Registration of Homeopathic Products) Order 1994 (S.I. 1994/102) which was revoked and replaced by the Medicines (Advisory Board on the Registration of Homeopathic Products) Order 1995 (S.I. 1995/309), as amended by the Medicines (Advisory Board on the Registration of Homeopathic Products) Order 2006 (S.I. 2006/2386), pursuant to the powers contained in section 4 of the Medicines Act 1968 as amended by the Part 1 of Schedule 11 to the Medicines Regulations 2012.

2. The Board changed on the 1st November 2012 from being an Advisory Non-Department Public Body (ANDPB) to an MHRA expert Committee

   Its terms of reference are:

   a) To give advice on safety and quality in relation to any homeopathic medicinal product for human use, in respect of which a certificate of registration has been granted or applied for.

   b) To give advice on safety, quality and indications for use within the UK homeopathic tradition in relation to any homeopathic medicinal product for human use,

      i) in respect of which a marketing authorisation has been granted or has been applied for, or

      ii) in respect of which a licence of right has been granted.

## MEMBERSHIP

3. A list of the Board's current membership is at **Appendix I**.

## SECRETARIAT

4. The Secretariat is based at the Medicines and Healthcare products Regulatory Agency. A list of the secretariat is at **Appendix II**.

## MEETINGS

5. There were 3 meetings in 2017. Meetings were held at the Medicines and Healthcare Products Regulatory Agency, 151 Buckingham Palace Road, London SW1W 9SZ.

## COSTS

6. Members are entitled to claim an attendance fee of £325 per day (Chairman's fee £500). Travel and subsistence is also payable within Department of Health guidelines.

## SAFETY ISSUES

### Reporting of suspected adverse drug reactions

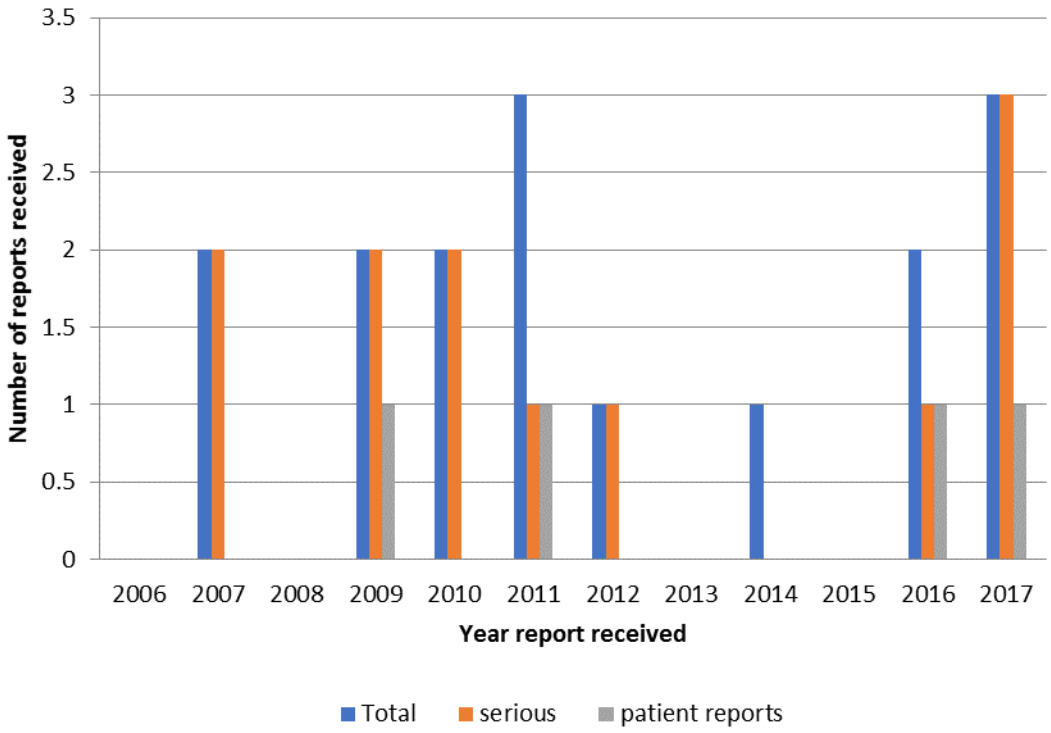
7. Suspected adverse reactions to medicinal products including homeopathic medicines are reported to the Medicines and Healthcare products Regulatory Agency (MHRA) on a voluntary basis by healthcare professionals and patients through the Yellow Card Scheme.

8. Information collected through the scheme is an important means of monitoring safety, acting as an early warning system for the identification of previously unrecognised adverse reactions and increasing knowledge of known adverse reactions.

**Table 1: Breakdown of the number of reports of suspected adverse reactions**

| Year received | Total number of reports received | Number of serious reports received | Number of reports received from patients |
|---|---|---|---|
| 2006 | 0 | 0 | 0 |
| 2007 | 2 | 2 | 0 |
| 2008 | 0 | 0 | 0 |
| 2009 | 2 | 2 | 1 |
| 2010 | 2 | 2 | 0 |
| 2011 | 3 | 1 | 1 |
| 2012 | 1 | 1 | 0 |
| 2013 | 0 | 0 | 0 |
| 2014 | 1 | 0 | 0 |
| 2015 | 0 | 0 | 0 |
| 2016 | 2 | 1 | 1 |
| 2017 | 3 | 3 | 1 |

**Figure 1: Breakdown of reports received between 2006 and 31 December 2017**




9. During 2017 three reports of adverse reactions suspected to be associated with the use of homeopathic medicines were received through the Yellow Card scheme for consideration by the Board. Unfortunately, due to the limited information provided it was not possible to establish whether the adverse reactions were causally associated with the homeopathic products or the method of administration. The MHRA will continue to monitor the issues.

10. The Board agreed that no new safety signals had been identified and that no regulatory action was required based on the case details presented.

11. The MHRA are continuing to actively seek ways to improve the level of reporting for medicines, including homeopathic medicines. The Board is grateful for the co-operation of those healthcare professionals and patients who submit reports of suspected adverse reactions and encourages the reporting of all suspected reactions to homeopathic medicines.

## SUMMARY

12. In 2017, the Board advised on one new application for a homeopathic national rules authorisation submitted under the National Rules Scheme.

13. The Board also received updates on European issues.

14. Tables showing the number of applications made for registration certificates and homeopathic marketing authorisations and the number of those referred to the Board for advice since it was established is at **Appendix III**.

## MEMBERSHIP OF THE ADVISORY BOARD ON THE REGISTRATION OF HOMEOPATHIC PRODUCTS

### Chair

**Professor Angus Mackay** OBE MA PhD (Cantab) MB ChB BSc (Pharmacol) FRCP (Edin) FRCPsych TPsych
Professor of Psychological Medicine, University of Glasgow

### Members

**Dr Ian Bailey**[1] BSc PhD FHEA
Teaching Fellow in Biochemical Sciences, Admissions tutor for Biomedical Sciences, Programme director in Applied Toxicology, University of Surrey

**Dr Steve Bennett Britton** MA MB BChir FRCP FRCPCH
Consultant Paediatrician, Sutton Coldfield

**Dr Robert J Boyle**[2] MB ChB MRCP PhD
Clinical Senior Lecturer in Paediatric Allergy, Imperial College London

**Dr Robert C G Bracchi** BSc MB BCh MD FRCGP
Retired General Practitioner

**Mrs Patricia Donnachie** RN OHNP MF (Hom) FF (Hom)
Service Support Manager Integrative Care, Advance Nurse Practitioner Integrative Care. NHS Centre for Integrative Care, Gartnavel Campus, Glasgow

**Professor Gillian M Eccleston** BSc PhD CChem FRSC FRPharmS
Emeritus Professor of Pharmaceutics, Strathclyde University

**Dr Michael R Evans**[3] MB ChB **(Vice Chair)**
Independent General Practitioner, St Luke's Therapy Centre Stroud, Faculty Member British Postgraduate Training in Anthroposophic Medicine

**Ms Susan Hunneyball BSc (Hons)**
Senior Associate, for and on behalf of Charles Russell Speechlys

**Professor George B Lockwood** BPharm (Hons) PhD MRPharmS
Professor of Pharmaceutical Sciences, School of Pharmacy & Pharmaceutical Sciences, University of Manchester

[1] Stepped down on 05/04/2017
[2] Stepped down on 16/04/2017
[3] Appointment ended on 31/12/2017

**Dr Frank Mulder**
General Practitioner, Helios Medical Centre, Bristol

**Dr Gary J Smyth** MB CHB DGM DMH DRCOG DFSRH MRCGP MFHOM
General Practitioner and Homeopathic Physician, Belfast, Northern Ireland

## MEMBERS OF THE ADVISORY BOARD'S ADMINISTRATIVE SECRETARIAT

**Miss Sue Harris**
Principal Assessor

**Dr Swati Bhat**
Medical Assessor

**Dr Elizabeth Griffiths**
Scientific Assessor

**Mr Jasbinder Sumal**
Pharmaceutical Assessor

**Mr Robin Fraser**
Unit Manager

**Ms N Nolen**
Secretary

| Homeopathic Registrations | | | | | |
|---|---|---|---|---|---|
| **Year** | **Applications Received** | **Applications Referred to ABRHP** | | | **Total** |
| | | **Provisional Refusal** | **Grant Advised** | **Conditional Grant** | |
| 1994 | 25 | 0 | 0 | 0 | 0 |
| 1995 | 24 | 10 | 0 | 3 | 13 |
| 1996 | 54 | 2 | 0 | 0 | 2 |
| 1997 | 88 | 2 | 0 | 1 | 3 |
| 1998 | 70 | 0 | 0 | 0 | 0 |
| 1999 | 73 | 3 | 0 | 3 | 6 |
| 2000 | 9 | 0 | 0 | 0 | 0 |
| 2001 | 13 | 0 | 0 | 0 | 0 |
| 2002 | 11 | 0 | 0 | 0 | 0 |
| 2003 | 0 | 0 | 2 | 0 | 2 |
| 2004 | 30 | 0 | 0 | 0 | 0 |
| 2005 | 13 | 0 | 0 | 0 | 0 |
| 2006 | 4 | 1 | 0 | 1 | 2 |
| 2007 | 1 | 0 | 0 | 0 | 0 |
| 2008 | 2 | 4 | 0 | 1 | 5 |
| 2009 | 0 | 0 | 0 | 0 | 0 |
| 2010 | 0 | 0 | 1 | 0 | 1 |
| 2011 | 0 | 0 | 0 | 0 | 0 |
| 2012 | 10 | 0 | 0 | 0 | 0 |
| 2013 | 1 | 0 | 0 | 0 | 0 |
| 2014 | 3 | 0 | 0 | 0 | 0 |
| 2015 | 0 | 1 | 0 | 0 | 1 |
| 2016 | 2 | 1 | 0 | 0 | 1 |
| 2017 | 0 | 0 | 0 | 0 | 0 |
| Total | 433 | 24 | 3 | 9 | |

| Homeopathic Marketing Authorisations | | | | | |
|---|---|---|---|---|---|
| Year | Applications Received | Applications Referred to ABRHP | | | Total |
| | | Provisional Refusal | Grant advised | Conditional Grant | |
| 2007 | 1 | 0 | 0 | 1 | 1 |
| 2008 | 2 | 0 | 0 | 2 | 2 |
| 2009 | 5 | 0 | 1 | 2 | 3 |
| 2010 | 10 | 1 | 1 | 7 | 9 |
| 2011 | 17 | 0 | 2 | 10 | 12 |
| 2012 | 8 | 0 | 0 | 8 | 8 |
| 2013 | 4 | 0 | 0 | 11 | 11 |
| 2014 | 3 | 1 | 0 | 3 | 4 |
| 2015 | 0 | 0 | 0 | 2 | 2* |
| 2016 | 3 | 0 | 0 | 0 | 0 |
| 2017 | 0 | 0 | 0 | 1 | 1 |
| Total | 53 | 2 | 4 | 47 | |

*Received pre-2015

# HERBAL MEDICINES ADVISORY COMMITTEE ANNUAL REPORT 2017

## INTRODUCTION / BACKGROUND

1. The Herbal Medicines Advisory Committee ("the Committee") was established under the powers contained in section 4 of the Medicines Act 1968 as amended by Part 1 of Schedule 11 to the Medicines Regulations 2012, and the Committee was formally created on 30 October 2005. The functions of the Committee are set out in the Herbal Medicines Advisory Committee Order 2005.

2. The Committee changed on the 1st November 2012 from being an Advisory Non-Departmental Public Body (ANDPB) to an MHRA Expert Committee. Its terms of reference are:

3. The Herbal Medicines Advisory Committee advises on the safety, quality and efficacy, in relation to human use, of:

    (a) herbal medicinal products eligible for registration under the simplified traditional use registration procedure established under European Directive 2004/24/EC and;

    (b) unlicensed herbal medicinal products (unless it is subject to an application for a marketing authorisation, product licence or a homeopathic certificate of registration).

4. The Committee may also advise on the safety, quality and efficacy, in relation to human use, of herbal medicinal products which have a marketing authorisation, product licence or certificate of registration, or which are the subject of an application for such authorisation, licence or certificate, if Health Ministers or the licensing authority request such advice, or provide the Committee with information relating to that product.

5. The primary role of the Committee will be issues relating to safety and quality, since there is not a requirement for efficacy to be separately demonstrated in relation to registered traditional herbal medicines or unlicensed products sold under section 12 of the Medicines Act. However, efficacy is still relevant under the traditional herbal registration scheme, the pharmacological effects or efficacy of the medicinal product must be plausible on the basis of long-standing use and experience.

## CHAIRMAN/MEMBERS

6. A list of the Committee's current membership is at **Appendix I**.

## SECRETARIAT

The Secretariat is based at the Medicines and Healthcare products Regulatory Agency. A list of the secretariat is at **Appendix II**.

## MEETINGS

7. There were 2 meetings in 2017. Meetings were held at the Medicines and Healthcare products Regulatory Agency (MHRA), 151 Buckingham Palace Road, London SW1W 9SZ.

8. Summary minutes of the meetings of the Committee can be found on the MHRA website (www.mhra.gov.uk >Committees>Medicines advisory bodies).

## COSTS

9. Members are entitled to claim an attendance fee of £325 per day (Chairman's fee £500). Travel and subsistence is also payable within Department of Health guidelines.

## TRADITIONAL HERBAL REGISTRATIONS

### Applications considered

10. During the year, the Committee considered and advised on one new application.

Table 1 lists the number of applications received which were referred to HMAC.

**Table 1: Number of Traditional Herbal Registrations**

| Year received | Number of applications received | Number of applications referred to HMAC | Number of applications approved |
|---|---|---|---|
| 2006 | 14 | 2 | 1 |
| 2007 | 17 | 4 | 6 |
| 2008 | 20 | 2 | 18 |
| 2009 | 47 | 6 | 22 |
| 2010 | 88 | 4 | 36 |
| 2011 | 52 | 5 | 66 |
| 2012 | 47 | 2 | 43 |
| 2013 | 169 | 2 | 126 |
| 2014 | 6 | 3 | 8 |
| 2015 | 9 | 2 | 11 |
| 2016 | 3 | 2 | 4 |
| 2017 | 7 | 1 | 6 |

## SAFETY ISSUES

### Reporting of suspected adverse drug reactions

11. Suspected adverse reactions to medicinal products including herbal medicines are reported to the Medicines and Healthcare products Regulatory Agency (MHRA) on a voluntary basis by healthcare professionals and patients through the Yellow Card Scheme. Reports are also submitted as a legal requirement by companies holding Marketing Authorisations or Traditional Herbal Registrations.

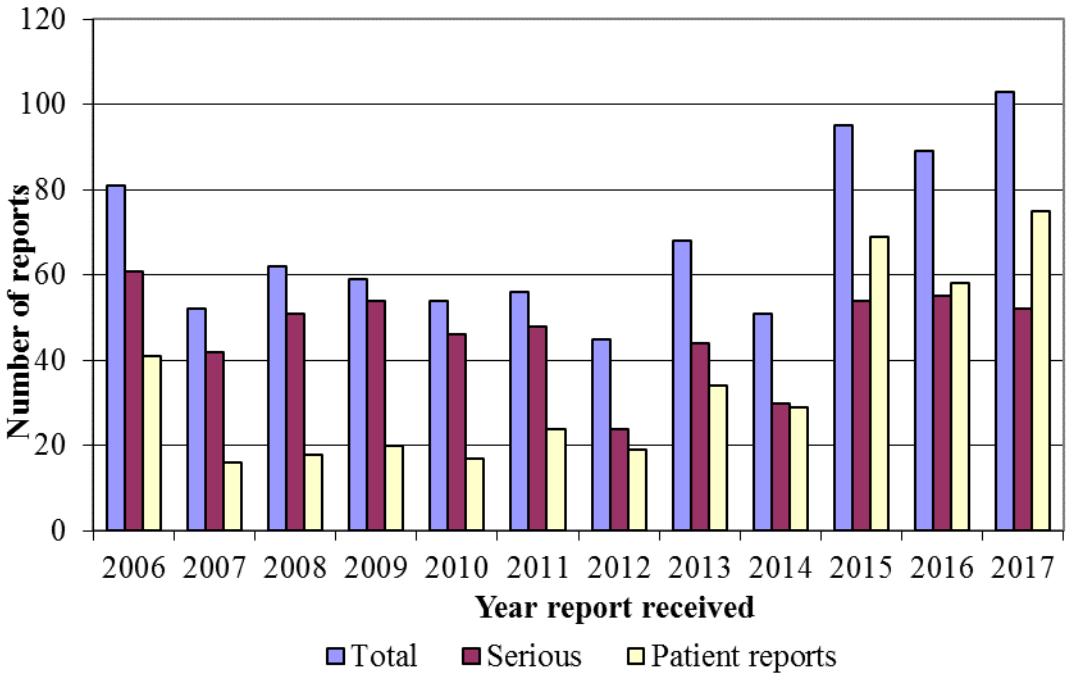
12. Information collected through the scheme is an important means of monitoring safety, acting as an early warning system for the identification of previously unrecognised adverse reactions and increasing knowledge of known adverse reactions.

13. During 2017 the Committee reviewed details of all adverse reactions which were suspected to be associated with herbal medicinal products. The total number of reports provided in Table 2 excludes products which are considered to be foods, devices, cosmetics, homeopathic products, licensed medicines not considered to be herbal medicines and unlicensed products which contain non-herbal ingredients such as animal parts. This data is also presented in Figure 1 below.

**Table 2: Reports of suspected adverse reactions**

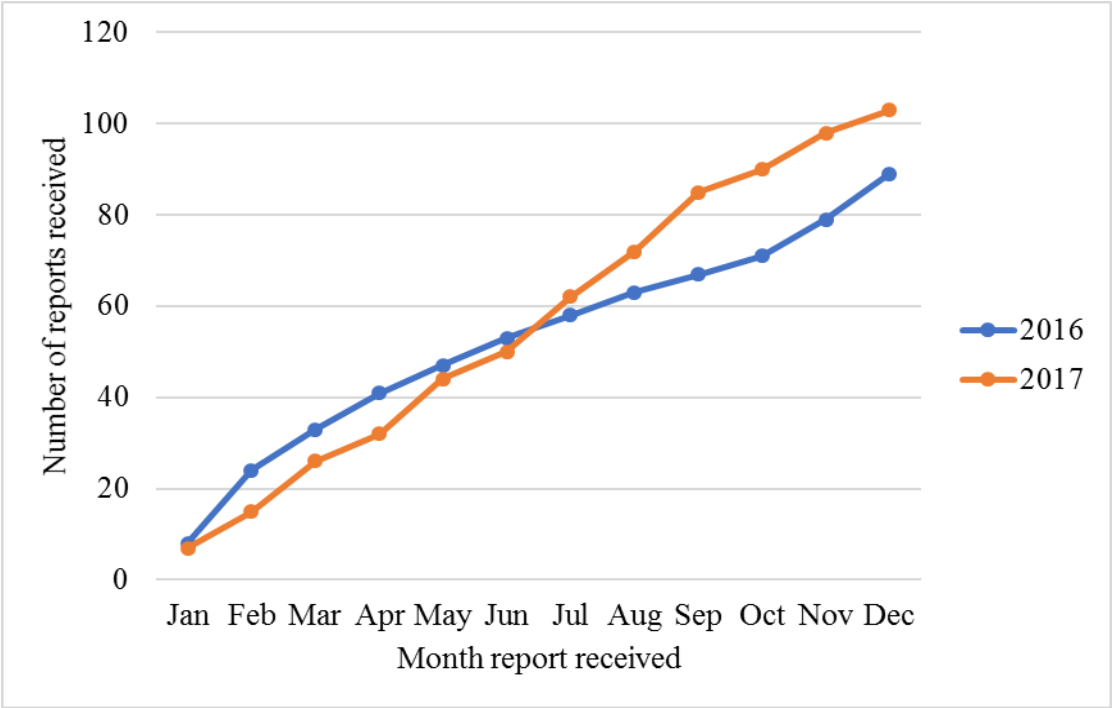
| Year received | Total number of reports received | Number of serious reports received | Number of reports received from patients |
|---|---|---|---|
| 2006 | 81 | 61 | 41 |
| 2007 | 52 | 42 | 16 |
| 2008 | 62 | 51 | 18 |
| 2009 | 59 | 54 | 20 |
| 2010 | 54 | 46 | 17 |
| 2011 | 57 | 48 | 24 |
| 2012 | 45 | 24 | 19 |
| 2013 | 68 | 44 | 34 |
| 2014 | 51 | 30 | 29 |
| 2015 | 95 | 54 | 69 |
| 2016 | 89 | 55 | 58 |
| 2017 | 103 | 52 | 75 |

**Figure 1: Breakdown of reports received between 2006 and 31 December 2017**




14. The Committee is grateful for the co-operation of those healthcare professionals and patients who submit reports of suspected adverse reactions and encourages the reporting of all suspected reactions to herbal medicines. A direct comparison of cumulative reporting rates for 2016 and 2017 is provided in figure 2 below.

**Figure 2: Cumulative number of reports received by month for 2016 and 2017**



15. Healthcare professionals and patients are continuing to submit reports through the Yellow Card scheme about suspected adverse reactions involving a range of herbal medicines, with patients increasingly reporting problems directly via the Yellow Card scheme.

16. Patients (or their family members) submitted the largest proportion of Yellow Card reports received in 2017 (73% of the total). The majority of patient reports were submitted directly to the Yellow Card scheme (n=60) but some were received via the Traditional Registration Holders (n=15).

17. The proportion of serious reports received in 2017 for herbal medicines is approximately 50%, which is slightly lower than 2016.

18. The MHRA are continuing to actively seek ways to improve the level of reporting for herbal medicines. It is recognised that the continued success of the Yellow Card Scheme depends on the willingness of healthcare professionals and patients to report suspected ADRs and that the Committee supports the ongoing activities of the MHRA to promote the scheme.

## POLICY ISSUES

19. The Committee received updates on the on-going consideration of the regulation of herbal medicines and practitioners.

## CONSIDERATION OF OTHER MATTERS

20. During the year, the Committee noted reports, Community Monographs and Public Statements from the Herbal Medicinal Products Committee meetings.

## Appendix I

## MEMBERSHIP OF THE HERBAL MEDICINES ADVISORY COMMITTEE

### Chair

**Professor Philip A Routledge** OBE MD FRCP FRCPE FBTS FRSB FAcadMEd FRCGP(Hon) FFPM(Hon) HonFBPhS
Professor of Clinical Pharmacology and Head of the Department of Pharmacology, Therapeutics and Toxicology, Cardiff University and Honorary Consultant Physician/Clinical Pharmacologist in Cardiff and Vale University Health Board

### Members

**Dr Robert C G Bracchi** BSc MB BCh MD FRCGP
Retired General Practitioner

**Dr Paul D Bremner** PhD BSc MBA SFHEA
Senior Lecturer, De Montfort University

**Ms Alison M Denham** MA FNIMH FHEA
Herbal Practitioner and Senior Lecturer in Herbal Medicine, University of Central Lancashire, Preston

**Dr Michael R Evans** MB ChB
Independent General Practitioner, St Luke's Therapy Centre Stroud, Faculty Member British Postgraduate Training in Anthroposophic Medicine

**Dr Shantha B W Godagama** DAMS MBAcC MF (hom) MAcF FAMA (UK)
Ayurvedic physician, Qualified Acupuncturist, Founder of Ayurvedic Medical Association U.K., College of Ayurveda, Author of Hand Book of Ayurveda, Director of the Ayurvedic Centre, Hale Clinic, London.

**Professor Paul T C Harrison**[4] BSc PhD CBiol FSB FBTS
Visiting Professor at Cranfield University; Director of PTCH Consultancy Ltd and IEH Consulting Ltd

**Professor Michael Heinrich** MA MSc PhD
Professor and Head of Centre, UCL School of Pharmacy, University of London

**Professor Peter Hylands** BPharm PhD FRSC
Director, Institute of Pharmaceutical Science, King's College London

[4] Appointment ended on 01/08/2017

**Professor John Francis Mayberry** DSc MD LLM FRCP
Consultant Physician, University Hospitals of Leicester NHS Trust;
Professor of Gastroenterology, University of Leicester

**Dr Barbara A Pendry** PhD BSc (Hons) PGCE MNIMH
Principal Lecturer, Herbal Practitioner and Programme Leader for Herbal Medicine at the University of East London

**Mrs Farrah Pradhan**
Lay Member. Invited Reviews Coordinator at the Royal College of Obstetricians and Gynaecologists

**Professor Raymond J Playford** MB BS PhD FRCP FAcadMedSci
Professor of Medicine, Plymouth University & Hon Consultant, Plymouth Hospitals NHS Trust

**Dr Deborah J Shaw** BSc (Hons) PhD
Independent Consultant on Herbal Safety and Pharmacovigilance

**Dr David Tuthill** MB BCh FRCPCH
Consultant Paediatrician, Children's Hospital for Wales, Cardiff

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

**Dr Jidong Wu** MB MSc PhD MATCM
Senior Lecturer and Programme Advisor in Traditional Chinese Medicine at Middlesex University

**Dr Kaicun Zhao** MB MSc PhD
Programme Leader, Traditional Chinese Medicine, Department of Mental Health, Social Work and Integrative Medicine, Middlesex University London

### Observers

**Professor Patricia McGettigan** BSc(Pharmacy) MD FRCPI FRACP SFHEA
Clinical Pharmacologist at European Medicines Agency and Reader in Clinical Pharmacology and Medical Education, Barts & The London School of Medicine and Dentistry

## Appendix II

### Members of the Committee's Administrative Secretariat

**Dr L Anderson**
Principal Assessor

**Mrs L Henderson**
Safety

**Mr R Fraser**
Unit Manager

**Ms E Agca**
Secretary

# 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 or the 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.

# ADVISORY BOARD ON THE REGISTRATION OF HOMEOPATHIC PRODUCTS: MEMBERS HAVE DECLARED CURRENT PERSONAL AND NON-PERSONAL INTERESTS IN THE PHARMACEUTICAL INDUSTRY AS FOLLOWS:

| | PERSONAL INTERESTS | | NON-PERSONAL INTERESTS | | | |
|---|---|---|---|---|---|---|
| **MEMBER** | **NAME OF COMPANY** | **NATURE OF INTERESTS** | **NAME OF COMPANY** | **NATURE OF INTERESTS** | **WHETHER CURRENT** | **ADDITIONAL INFORMATION** |
| Professor Angus Mackay | None | None | None | None | No | None |
| Dr Ian Bailey | | | | | | |
| Dr Steve Bennett Britton | None | None | None | None | No | None |
| Dr Robert Boyle | None | None | None | None | No | None |
| Dr Robert C G Bracchi | None | None | None | None | No | None |
| Mrs Patricia Donnachie | None | None | None | None | No | None |
| Professor Gillian Eccleston | None | None | None | None | No | None |
| Professor Michael Evans | None | None | None | None | No | None |
| Ms Susan Hunneyball | None | None | None | None | No | None |
| Professor George B Lockwood | None | None | None | None | No | None |
| Dr Frank A Mulder | None | None | None | None | No | None |
| Dr Gary J Smyth | None | None | None | None | No | None |

# HERBAL MEDICINES ADVISORY COMMITTEE: MEMBERS HAVE DECLARED CURRENT PERSONAL AND NON-PERSONAL INTERESTS IN THE PHARMACEUTICAL INDUSTRY AS FOLLOWS:

| | PERSONAL INTERESTS | | NON-PERSONAL INTERESTS | | | |
|---|---|---|---|---|---|---|
| **MEMBER** | **NAME OF COMPANY** | **NATURE OF INTERESTS** | **NAME OF COMPANY** | **NATURE OF INTERESTS** | **WHETHER CURRENT** | **ADDITIONAL INFORMATION** |
| Professor Philip Routledge (Chair) | None | None | None | None | No | None |
| Dr Robert C G Bracchi | None | None | None | None | No | None |
| Dr Paul Bremner | None | None | None | None | No | None |
| Mrs Alison Denham | None | None | None | None | No | None |
| Professor Michael Evans | None | None | None | None | No | None |
| Dr Shantha Godagama | None | None | None | None | No | None |
| Professor Paul Harrison | None | None | None | None | No | None |
| Professor Michael Heinrich | None | None | Fa Schwabe, Germany | Charitable donation for research on the quality of herbal medical products and links with value chains of such products Y | Yes | Non-pharamceutical sector - Bayer Consumer Health Care - Conference presentation on ethnopharmacological research (July 2017). Participation in a symposium |
| | | | Pukka Herbs, UK | Turmeric products - Sponsorship of a student project on the quality of Curcuma longa to the UCL School of Pharmacy | No | |
| Professor Peter Hylands | | | | | | |
| Professor John Frances Mayberry | None | None | None | None | No | None |
| Dr Barbara Ann Pendry | None | None | None | None | No | None |
| Mrs Farrah Pradhan | None | None | None | None | No | None |
| Professor Raymond J Playford | | | | | | |
| Dr Deborah Shaw | None | None | None | None | No | None |

| | PERSONAL INTERESTS | | NON-PERSONAL INTERESTS | | | |
|---|---|---|---|---|---|---|
| **MEMBER** | **NAME OF COMPANY** | **NATURE OF INTERESTS** | **NAME OF COMPANY** | **NATURE OF INTERESTS** | **WHETHER CURRENT** | **ADDITIONAL INFORMATION** |
| Dr David Tuthill | None | None | None | None | No | None |
| Professor Heather M Wallace | None | None | None | None | No | Owns less than 0.1% shares in Novabiotics, Precious Cells and Antoxis, and is a Director in CellProTx. The companies are all spin outs from the university and I receive no financial benefit. |
| Dr Jidong Wu | None | None | None | None | No | None |
| Dr Kaicun Zhao | None | None | None | None | No | None |

**Contact for information about these reports:**

**Expert Committee Support**
**Medicines & Healthcare products Regulatory Agency**
**151 Buckingham Palace Road, London, SW1W 9SZ**

**020 3080 6060**

**ExpertCommitteeSupport@mhra.gov.uk**