Advisory Board on the Registration of Homeopathic Products

Herbal Medicines Advisory Committee

Annual Report 2021

Medicines and Healthcare products Regulatory Agency

Advisory Board on the Registration of Homeopathic Products

Herbal Medicines Advisory Committee

Annual Reports 2021

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FOREWORD BY GRAHAM COOKE, INTERIM CO-CHAIR OF THE MEDICINES AND HEALTHCARE PRODUCTS REGULATORY AGENCY

I am delighted to present the Annual Reports of the Advisory Board for the Regulation of Homeopathic Products and the Herbal Medicines Advisory Committee.

The expert committees provide critical independent scientific advice for the effective regulation of medicinal products in the UK. Importantly, these committees continue to operate with the highest standards of conduct, independence and fairness to help ensure that the medicinal products we use are safe.

On behalf of the agency, I would also like to offer my sincere thanks to the Chair and Members for their professional expertise, commitment and focus on protecting or improving patient health whilst they have been performing their public duties on these committees.

Professor Graham Cooke
Interim Co-Chair
MHRA

ADVISORY BOARD ON THE REGISTRATION OF HOMEOPATHIC PRODUCTS ANNUAL REPORT 2021

INTRODUCTION

1. The Advisory Board on the Registration of Homeopathic Products (ABRHP) was established in 1994.

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

   Its terms of reference are to give advice to the Licensing Authority:

   a) 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 ABRHP current membership is at **Appendix I**.

SECRETARIAT

4. The Secretariat is based at the Medicines and Healthcare products Regulatory Agency (MHRA).

MEETINGS

5. There were three meetings in 2021. Meetings were held virtually using MS teams.

6. Summary minutes of the meetings can be found on the MHRA website.

COSTS

7. Members are entitled to claim an attendance fee of £325 per day (Chair's fee £500). Travel and subsistence are also payable within the MHRA guidelines.

Reporting of suspected adverse drug reactions

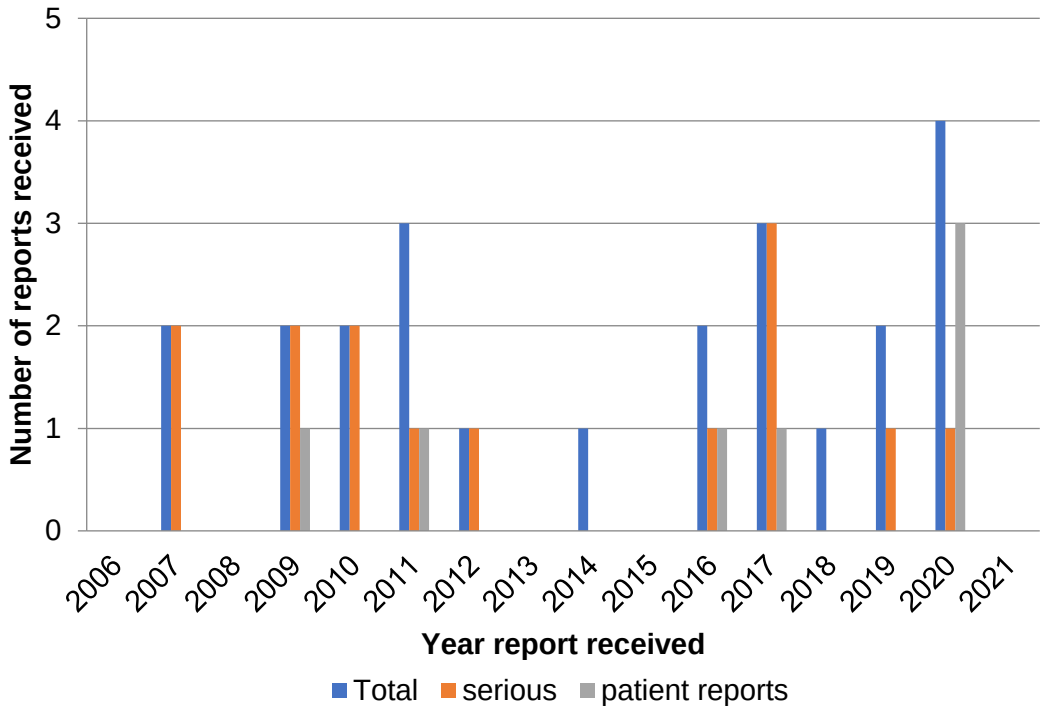
8. Suspected adverse reactions to medicinal products including homeopathic medicines are reported to the MHRA on a voluntary basis by healthcare professionals and patients through the Yellow Card Scheme.

9. 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
2018	1	0	0
2019	2	1	0
2020	4	1	3
2021	0	0	0

Figure 1: Breakdown of reports received between 2006 and 2021



10. During 2021, no cases of possible adverse reactions to homeopathic products were received through the Yellow Card Scheme. The ABRHP did not identify any new safety signals and no regulatory action was required due to safety concerns.

11. The MHRA will continue to monitor any adverse reactions received. In addition, further consideration will be given to possible allergic reactions suspected to be associated with teething granules to establish whether the product information should be updated.

12. The MHRA are continuing to actively seek ways to improve the level of reporting for medicines, including homeopathic medicines. The ABRHP 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.

CONSIDERATION OF OTHER MATTERS

13. The ABRHP also received updates on the Government's response to the Cumberlege Report and the Patient Involvement Strategy.

SUMMARY

14. In 2021, the ABRHP discussed products issued a Product Licence of Right transferring to the UK Homeopathic National Rules Scheme.

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

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

Vice Chair

Ms Sarah Mawhinney[1] Bsc (Hons), MPSNI, FPS, DF Hom (Pharm)
Community Pharmacist Northern Ireland

Members

Professor Susan Barker B.Pharm. (Hons), Ph.D., PGCHET
Head of the Medway School of Pharmacy, Medway School of Pharmacy, Universities of Greenwich and Kent at Medway. Kent

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 Renal and Integrative Care, Advance Nurse Practitioner Integrative Care. NHS Centre for Integrative Care, Gartnavel Campus, Glasgow

Ms Susan Hunneyball BSc (Hons)
Lay Member

Dr Jennifer Lenhart BSc MedSci., MB,ChB., MFHom, MA.
Associate Specialist Homeopathic Physician, The Royal London Hospital for Integrated Medicine, UCLH NHS Trust, London

Professor George B Lockwood [2] BPharm (Hons) PhD MRPharmS
Professor of Pharmaceutical Sciences, Division of Pharmacy & Optometry School of Health Sciences, University of Manchester

Dr Frank Mulder[3]
General Practitioner, Helios Medical Centre, Bristol

Dr Gary J Smyth MB ChB DGM DMH DRCOG DFSRH MRCGP FFHom
General Practitioner and Homeopathic Physician, Belfast, Northern Ireland

[1] From 23/03/2021
[2] End of Appointment 18/10/2021
[3] End of Appointment 19/07/2021

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	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
2018	0	0	0	1	1
2019	0	0	0	0	0
2020	0	0	0	0	0
2021	0	0	0	0	0
Total	467	20	6	56	82

*Received pre-2015

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
2018	0	0	0	0	0
2019	1	0	0	1	1
2020	0	0	0	0	0
2021	0	0	0	0	0
Total	54	2	4	48	54

*Received pre-2015

HERBAL MEDICINES ADVISORY COMMITTEE ANNUAL REPORT 2021

INTRODUCTION/BACKGROUND

1. The Herbal Medicines Advisory Committee (HMAC) was established on 30 October 2005. The functions of the Committee are set out in the Herbal Medicines Advisory Committee Order 2005.

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

3. The HMAC advises on the safety, quality and efficacy, in relation to human use, of:

    3.1 herbal medicinal products eligible for registration under the simplified traditional use registration procedure set out in Part 7 of the Human Medicines Regulations 2012; and

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

4. The HMAC 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 HMAC with information relating to that product.

CHAIR/MEMBERS

5. A list of the HMAC's current membership is at **Appendix I**.

SECRETARIAT

6. The Secretariat is based at the Medicines and Healthcare products Regulatory Agency (MHRA).

MEETINGS

7. There were three meetings in 2021. Meetings were held virtually using MS teams.

8. Summary minutes of the meetings of the HMAC can be found on the MHRA website.

COSTS

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

TRADITIONAL HERBAL REGISTRATIONS

10. During the year, two applications were approved; none were referred to HMAC. Table 1 lists the number of Traditional Herbal Registrations (THR) applications received.

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
2018	10	1 (Variation)	7
2019	0	0	4
2020	3	0	1
2021	0	0	2

SAFETY ISSUES

Reporting of suspected adverse drug reactions

11. Suspected adverse reactions to medicinal products including herbal medicines are reported to the 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 THRs.

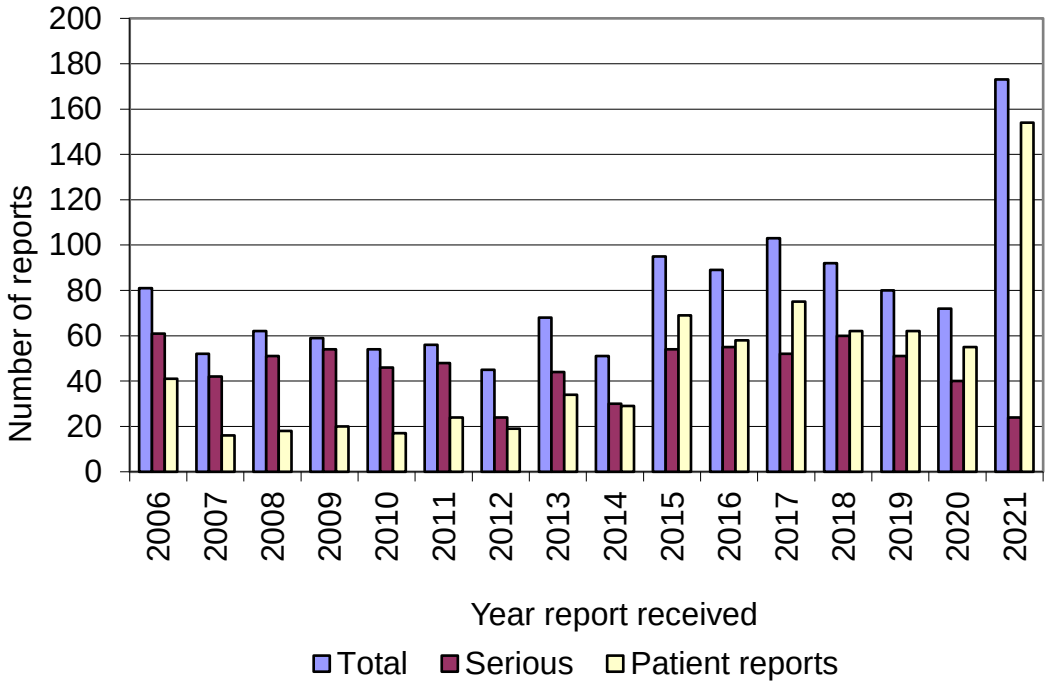
12. Information collected through the scheme is an important means of monitoring safety, acting as an early warning system for the identification of previously unrecognised adverse reactions and increasing knowledge of known adverse reactions.

13. At the meetings in 2021 the HMAC reviewed details of adverse reactions received during the period 1 January to 31 December 2021. A total of 173 reports which were suspected to be associated with herbal medicinal products were reviewed. The number of reports received each year through the Yellow Card scheme 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.

14. **Table 2: Breakdown of reports received of suspected adverse reactions**

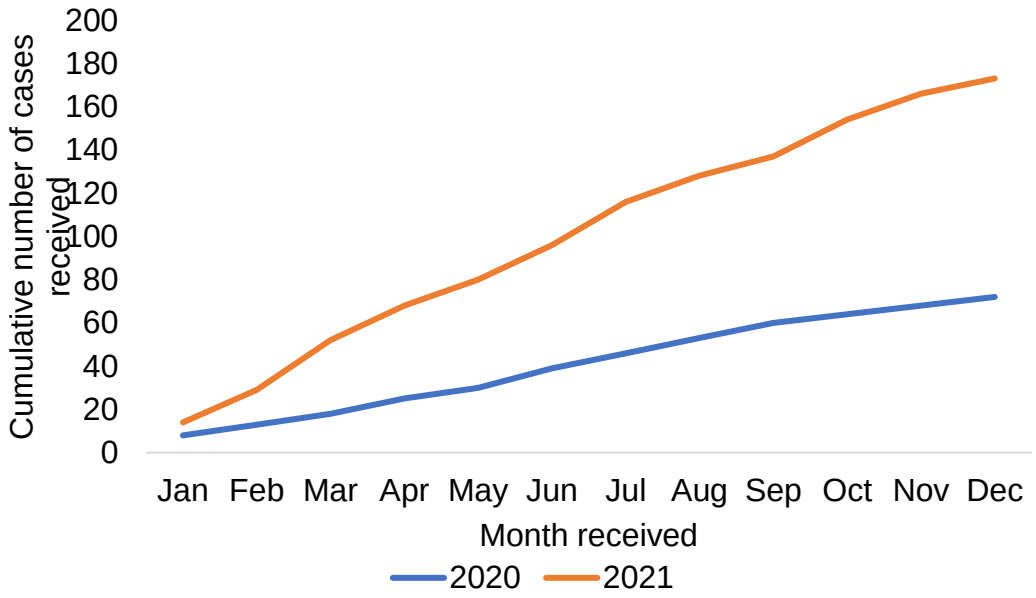
Year received	Total number of reports received	Number of serious reports received	Number of reports received from patients
2006	81	61	41
2007	52	42	16
2008	62	51	18
2009	59	54	20
2010	54	46	17
2011	57	48	24
2012	45	24	19
2013	68	44	34
2014	51	30	29
2015	95	54	69
2016	89	55	58
2017	103	52	75
2018	92	60	62
2019	80	51	62
2020	72	40	55
2021	173	24	154

Figure 1: Breakdown of reports received between 1 January 2006 and 31 December 2021



The HMAC 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 2020 and 2021 is provided in Figure 2 below.

Figure 2: Cumulative number of reports received by month for 2020 and 2021



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 2021 (88% of the total). The majority of patient reports were submitted via the Traditional Herbal Registration Holders (n=127) rather than directly to the Yellow Card scheme (n=27).

17. The proportion of serious reports received in 2021 for herbal medicines is approximately 14%, which is significantly lower than last year.

18. From January 2021, the companies holding authorisations for medicines (including herbal medicines) were required to submit both serious and non-serious reports of suspected adverse reactions directly to the MHRA. This change in reporting requirements directly contributed to the higher number of reports received in 2021.

19. 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 Adverse Drug Reactions and that the HMAC supports the ongoing activities of the MHRA to promote the scheme.

CONSIDERATION OF OTHER MATTERS

20. During the year, the HMAC noted reports, European Union Herbal Monographs and Public Statements from the Committee on Herbal Medicinal Products (HMPC) meetings.

21 The HMAC also received updates on the Government’s response to the Cumberlege Report and the Patient Involvement Strategy.

MEMBERSHIP OF THE HERBAL MEDICINES ADVISORY COMMITTEE

Chair

Professor Raymond J Playford MB BS PhD FRCP FAcadMedSci

Professor of Molecular Medicine, School of Biomedical Sciences, University of West London, Visiting Consultant St Georges University Hospital NHS Foundation Trust & Visiting Research Scientist Queen Mary, University of London

Vice Chair

Professor Heather M Wallace PhD FRCPath FRSC FSB FBPharmacolS FBTS European Registered Toxicologist
Professor of Biochemical Pharmacology and Toxicology, School of Medicine, Medical Sciences and Nutrition, Institute of Medical Sciences, University of Aberdeen

Members

Dr Raghav Baliga BMAS MSc Mres
Director and Ayurveda Consultant, Baliga Ayurveda, London

Miss Louisa Jane Blakeway MBRCP BA
Health Care Practitioner for Gloucestershire Health and Care NHS Foundation Trust, Gloucestershire Recovery in Psychosis Team
Self Employed Business Owner of Wholistic Therapies – Complementary Therapy Practice Allergy Therapy and Nutritional Balancing Dip and Reflexology Dip

Dr Paul D Bremner PhD BSc MBA SFHEA
Associate Professor, De Montfort University

Professor Christopher Goldring BSc PhD
Chair of Molecular and Cellular Pharmacology, Department of Pharmacology and Therapeutics, University of Liverpool

Professor Michael Heinrich[4] MA MSc PhD
Professor and Head of Centre, UCL School of Pharmacy, University of London

Dr Barbara A Pendry[5] PhD BSc (Hons) PGCE MNIMH
Principal Lecturer, Herbal Practitioner and Programme Leader for Herbal Medicine at the University of East London

[4] End of Appointment 31/12/2021
[5] End of Appointment 31/08/2021

Dr Edward Thompson MB ChB, MA, MRCGP, MF Hom, MARH, FURHP, MBRCP
General Practitioner, Emergency Medicine GP, CHDD Tutor Leicester Medical School, Holistic General Practice May Tree Clinic

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

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

Dr James Coulson[6] BSc (Hons), MB BCh (Hons), LLM, MD, MFPH, MRSB, FRCP, FRCPE, Clinical Reader in Clinical Pharmacology, Therapeutics & Toxicology, Cardiff University. Honorary Professor of Clinical Pharmacology & Toxicology, Cardiff Metropolitan University. (Visiting) Professor of Clinical Pharmacology, University of South Wales. Honorary Consultant Physician, Clinical Pharmacologist & Toxicologist, Cardiff & Vale University Health Board. Interim Clinical Director of the All Wales Therapeutics & Toxicology Centre

Professor Colin W Wright[7] BPharm MSc PhD FRPharmS Professor of Pharmacognosy, School of Pharmacy and Medical Sciences, University of Bradford.

[6] Appointed 01/10/2021
[7] Appointed 01/10/2021

CODE OF PRACTICE FOR CHAIRMEN AND MEMBERS OF THE COMMISSION ON HUMAN MEDICINES, CERTAIN COMMITTEES AND EXPERT ADVISORY GROUPS IN USE UNTIL SEPTEMBER 2022

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 the 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.

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.

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.

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 the 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 chairmen 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 the 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 the 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 chairmen 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 Chemistry, 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 chairmen 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 serve, 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 the chairmen and members of the CHM, HMAC and ABRHP (including the chairmen of the Chemistry, 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 be 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 chairmen 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 the chairmen and members of EAGs, apart from the chairmen of the three 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.

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.

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 chairmen 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.

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 Chairmen'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 chairmen'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.

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.

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.

NEW CODE OF PRACTICE FOR EXPERT COMMITTEES

In 2022, the MHRA led a public consultation exercise on a set of proposals to improve and strengthen the Code of Practice on conflicts of interest for experts who provide advice on which decisions about the regulation of medicines and medical devices may be based, or provide advice on standards used in the British Pharmacopeia.

In response to the public consultation, a new Code of Practice was drafted to clarify the ways that chairs, members, co-opted members, invited and patient experts and the public can participate in meetings and discussions of the advisory committees and working groups.

The new Code has now replaced the version shown above. It is published alongside the consultation response document and is available via the link: https://www.gov.uk/government/consultations/consultation-on-a-new-code-of-practice-for-the-expert-advisory-committees

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**
Angus Mackay	None	N/A	None	N/A	N/A	None
Sarah Mawhinney	None	N/A	None	N/A	N/A	None
Susan Barker	None	N/A	None	N/A	N/A	None
Robert Bracchi	None	N/A	None	N/A	N/A	None
Patricia Donnachie	None	N/A	None	N/A	N/A	None
Susan Hunneyball	None	N/A	None	N/A	N/A	Writes articles published in the Chemist and Druggist magazine, a trade magazine for pharmacists but receives no payment for those articles. The information referred to is in the public domain. Ms

MEMBER	PERSONAL INTERESTS		NON-PERSONAL INTERESTS			
	NAME OF COMPANY	NATURE OF INTERESTS	NAME OF COMPANY	NATURE OF INTERESTS	WHETHER CURRENT	ADDITIONAL INFORMATION
						Hunneyball makes it clear that these are her personal views and reflections and references all sources of information used
Jennifer Lenhart	None	N/A	None	N/A	N/A	None
George Lockwood	None	N/A	None	N/A	N/A	None
Frank A Mulder	None	N/A	None	N/A	N/A	None
Gary Smyth	None	N/A	None	N/A	N/A	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**
Raymond John Playford	None	N/A	None	N/A	N/A	I am a part time employee of Pantheryx Inc., a bovine colostrum manufacturing and distribution company based in Boulder, Co., USA. This company does not manufacture or distribute pharmaceutical products.
Heather Wallace	None	N/A	CellProTx	Director	Yes	None
Raghavendra Baliga	None	N/A	None	N/A	N/A	As a practitioner of Ayurvedic medicine, I formulate and prescribe herbal therapies. I source raw ingredients from a large range of

	PERSONAL INTERESTS		NON-PERSONAL INTERESTS			
MEMBER	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**WHETHER CURRENT**	**ADDITIONAL INFORMATION**
						direct producers and suppliers. I do not have any business relationship with any of these suppliers, except as a purchaser.
Louisa Blakeway	None	N/A	None	N/A	N/A	None
Paul Bremner	None	N/A	None	N/A	N/A	None
Chris Goldring	None	N/A	Innovative Medicines Initiative project: Transbioline https://transbioline.com/project/	Grant	Yes	None
			7 Pharmaceutical Companies: Pfizer, MSD, Roche, Eli Lilly, Novartis, Janssen, Sanofi-Aventis			
			Innovative Medicines Initiative project:	Grant	Yes	

MEMBER	PERSONAL INTERESTS		NON-PERSONAL INTERESTS			
	NAME OF COMPANY	**NATURE OF INTERESTS**	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**WHETHER CURRENT**	**ADDITIONAL INFORMATION**
			TransQST http://transqst.org/ 9 Pharmaceutical Companies: Eli Lilly, Abbvie, Servier, Sanofi-Aventis, AZ, GSK, Janssen, Orion, B.I.			
			Merck	Grant	Yes	
			KalVista Pharmaceuticals	Consultancy paid into University of Liverpool research account	Yes	
Michael Heinrich	None	N/A	None	N/A	N/A	None
Barbara Pendry	None	N/A	None	N/A	N/A	None
Edward Thompson	None	N/A	None	N/A	N/A	None

	PERSONAL INTERESTS		NON-PERSONAL INTERESTS			
MEMBER	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**WHETHER CURRENT**	**ADDITIONAL INFORMATION**
David Tuthill	Cardiff Paediatrics	Work as Dr and Director	Diagenics	I organise the South Wales Paediatric Allergy Forum in Cardiff once per year and have this meeting sponsored by a variety of allergy companies into a departmental endowment fund. I receive no personal payment.	Yes	None
			Mead Johnson,	I organise the South Wales Paediatric Allergy Forum in Cardiff once per year and have this meeting sponsored by a variety of allergy companies into a departmental endowment fund.		

	PERSONAL INTERESTS		NON-PERSONAL INTERESTS			
MEMBER	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**WHETHER CURRENT**	**ADDITIONAL INFORMATION**
			Nutritcia,	I receive no personal payment. I organise the South Wales Paediatric Allergy Forum in Cardiff once per year and have this meeting sponsored by a variety of allergy companies into a departmental endowment fund. I receive no personal payment.		
			Allergy therapeutics	I organise the South Wales Paediatric Allergy Forum in Cardiff once per year and have this meeting sponsored by a variety of allergy companies into a		

	PERSONAL INTERESTS		NON-PERSONAL INTERESTS			
MEMBER	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**WHETHER CURRENT**	**ADDITIONAL INFORMATION**
				departmental endowment fund. I receive no personal payment. I organise the South Wales Paediatric Allergy Forum in Cardiff once per year and have this meeting sponsored by a variety of allergy companies into a departmental endowment fund. I receive no personal payment.		
			Novartis			
Kaicun Zhao	None	N/A	None	N/A	N/A	None
James Coulson	Medicine, Scientific & Toxicology Consultancy Ltd	Director and shareholder	Amgen	Honorarium paid to NHS for producing educational		

				materials at a CPD event.		
Colin Wright	None	N/A	None	N/A	N/A	None

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