



## **Five Members of the Herbal Medicines Advisory Committee (HMAC)**

### **Information pack for applicants**

**Closing date: 12 noon on 19 February 2013**

**Reference no: EC12-08**

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## **Members of the Herbal Medicines Advisory Committee (HMAC)**

### **Overview**

#### **The role**

Members will need to possess or develop a working knowledge and understanding of the UK/European medicines regulatory procedures in relation to herbal medicines and will need to contribute by drawing on their expertise on meeting agenda items.

Candidates will have experience of committee membership and the ability to assimilate complex scientific information at short notice. In addition, candidates should have recent experience in one of the following; pharmacy including pharmaceutical quality and standards, pharmacognosy, phytochemistry, quality assurance of herbal medicinal products including analytical methods, as a herbal practitioner, as a toxicologist or as a consultant paediatrician (medically qualified) who is not a herbal practitioner.

For further information on the role of the Members see **Annex A**.

#### **HMAC**

The HMAC advises on the safety, quality and efficacy, in relation to human use of herbal medicinal products which are either eligible for registration or unlicensed.

For further information on the role of the HMAC see **Annex B**.

#### **Indicative timetable**

Advert:	w/c 17 December 2012
Closing date:	19 February 2013 at 12 noon
Shortlisting complete:	late February 2013
Interviews held:	early March 2013
Appointment start date:	To be confirmed

#### **Remuneration**

Members will receive £325 per meeting.

#### **Time commitment**

Approximately 1 day per month.

#### **Tenure of office**

Up to a maximum of three years.

## **Accountability**

Members are appointed by the Medicines and Healthcare products Regulatory Agency (MHRA)'s Senior Responsible Officer (Chair of the MHRA) and will be accountable to him for carrying out their duties and for their performance.

## **Diversity and equality of opportunity**

We value and promote diversity and are committed to equality of opportunity for all and appointments made on merit.

## **Key contacts:**

For information regarding the selection process, please contact:

Holly Wainwright  
Appointments Team  
Department of Health  
Quarry House  
Quarry Hill  
Leeds  
LS2 7UE  
Tel: 0113 254 6135  
Email: holly.wainwright@dh.gsi.gov.uk

For information regarding the role of HMAc and its Members please contact:

Email: Ms Ekash Paik  
Tel: 020 3080 6060  
Email: ecs.appointments@mhra.gsi.gov.uk

**Please quote reference EC12-08 on all correspondence.**

For further details on how to make an application, please see **Annex C**.

## Appointment of the Members

### Role and responsibilities of Members

Members of HMAc are required to:

- possess or develop a working knowledge and understanding of the UK/European medicines regulatory procedures in relation to herbal medicines;
- attend all scheduled and unscheduled meetings of HMAc (and to be present for the whole meeting);
- consider, comment and contribute by drawing on their individual expertise and judgement, as appropriate, on all agenda items and to assist the HMAc to frame clear and unequivocal advice to MHRA in accordance with the HMAc's terms of reference;
- be able and prepared to speak on a range of relevant issues and not just on their own areas of specialism;
- provide formal and informal advice to the MHRA between meetings when required; and
- contribute to and ensure that the HMAc's advice takes account of a wider view of risk - benefit, particularly as it is perceived by patients, carers and other members of the public.

### Qualities required for the role of Member

To be considered, you must be able to demonstrate that you have the qualities, skills and experience to meet all the essential criteria for appointment

#### Essential criteria

- Previous or current experience of committee membership.
- Be a skilled communicator.
- Be able to assimilate complex scientific information at short notice.
- Be able and prepared to contribute actively to the work of the HMAc.
- In addition potential professional members should be recognised by their peers as a leader in their field eg national academies and Royal Colleges. They should have extensive and recent experience in one of the following professions:
  - Pharmacy including pharmaceutical quality and standards.
  - Pharmacognosy, phytochemistry, quality assurance of herbal medicinal products including analytical methods.

- Herbal practitioner
- Toxicologist
- A consultant paediatrician (medically qualified) who is not a herbal practitioner.

### **Remuneration**

- £325 per meeting.
- Remuneration is taxable, and subject to National Insurance contributions.
- Those appointed will also be eligible to claim allowances, at rates set centrally, for travel and subsistence costs necessarily incurred on HMAAC business.
- Note: Impact of appointment on people in receipt of benefits. Your appointment may have an effect on your entitlement to benefits. If you are in receipt of benefits you should seek advice from the Department for Work and Pensions.

### **Time commitment**

Approximately one day per month.

### **Tenure of office**

Up to a maximum of three years.

### **Accountability**

Members are appointed by the MHRA's Senior Responsible Officer and will be accountable to him for carrying out their duties and for their performance.

### **Eligibility criteria**

There are circumstances in which an individual may not be considered for appointment. They include:

- people who have received a prison sentence or suspended sentence of 3 months or more in the last 5 years;
- people who are the subject of a bankruptcy restrictions order or interim order;
- anyone who has been dismissed by a public body within the past five years, other than by reason of redundancy;
- in certain circumstances, those who have had an earlier term of appointment terminated;
- anyone who is under a disqualification order under the Company Directors Disqualification Act 1986; and
- anyone who has been removed from trusteeship of a charity.

Further advice about disqualification for appointment can be provided by contacting Holly Wainwright on 0113 254 6135.

### **Conflict of Interests**

You should particularly note the requirement for you to declare any actual or potential conflict of interest you may have in carrying out the role of Member. Conflicts may relate to any relevant business interests, positions of authority or other connections with organisations relevant to the business of HMAc.

If you are aware of any potential conflicts prior to your appointment you should raise these during the process of your application. If an issue arises following your appointment you should ensure that you alert the MHRA's Senior Responsible Officer, to whom you will be accountable for your performance.

### **Standards in public life**

You will be expected to demonstrate a commitment to and an understanding of the value and importance of the seven principals of public life. All successful candidates will be asked to subscribe to *the code of practice for scientific advisory committees (CoPSAC)*; you can access this document at:

<http://www.bis.gov.uk/assets/BISPartners/GoScience/Docs/C/11-1382-code-of-practice-scientific-advisory-committees.pdf>.

### **Diversity and equality of opportunity**

We value and promote diversity and are committed to equality of opportunity for all and appointments made on merit.

## **HMAC role and responsibilities**

### **Background and Terms of Reference**

The Herbal Medicines Advisory Committee („the Committee“) was established under the powers contained in section 4 of the Medicines Act 1968 (now enshrined in the Human Medicines Regulations 2012/1916) and the Committee was formally created on 30 October 2005.

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

- herbal medicinal products eligible for registration under the simplified traditional use registration procedure established under European Directive 2004/24/EC and;
- unlicensed herbal medicinal products (unless it is subject to an application for a marketing authorisation, product licence or a homoeopathic certificate of registration).

The Committee changed from being an Advisory Non-Departmental Public Body (ANDPB) to an MHRA Expert Committee on the 1<sup>st</sup> November 2012 following the 2010 Cabinet Office Public Bodies review

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.

The role of the Committee will concern primarily 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 new 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.

### **The Future regulation of Herbal medicines: the Traditional Herbal Registration Scheme**

Historically most herbal medicines on the UK market were sold as unlicensed herbal remedies, exempt from licensing. In 2004 the EU Directive on traditional herbal medicinal products introduced a more systematic regulation and required Member States to put in place a simplified form of licensing regime.

Standards of quality and patient information are the same as for licensed medicines; safety is based mainly on bibliographic data and in place of the normal requirement for medicines to demonstrate efficacy, minor indications are permitted based on traditional use. The UK traditional herbal registration scheme is gathering momentum and we expect numbers to rise steadily.



## Making an application

### Overview

The appointment of Members to HMAAC are MHRA appointments. The Department of Health will manage the recruitment process in a way that is open and fair to all applicants and the appointment will be made on merit.

The interview panel will make recommendations to the MHRA on candidates they believe are 'appointable'. Taking into account feedback from the panel, the MHRA's Senior Responsible Officer will make the final decision on who he believes best meets the criteria for the role and will make the appointment.

### How to apply

All applicants are required to complete an application form. This is available online by visiting the DH website: [www.dh.gov.uk/appointments](http://www.dh.gov.uk/appointments) and searching for the vacancy EC12-08.

Alternative formats such as braille, large print and tape versions of this information pack and the application forms are available from

Holly Wainwright  
Tel: 0113 254 6135  
Email: [holly.wainwright@dh.gsi.gvo.uk](mailto:holly.wainwright@dh.gsi.gvo.uk)

If you wish to submit a paper copy of your application, or one in an alternative format, please send to:

Holly Wainwright  
Appointments Team (Room 2E29)  
Department of Health  
Quarry House  
Quarry Hill  
LEEDS  
LS2 7UE

All applications will be acknowledged by email and you will be contacted again after the closing date.

The Appointments Team must receive your completed application form **before 12 noon on 19 February 2013**.

## **Your personal information**

Your personal information will be held in accordance with the Data Protection Act 1998. You will not receive unsolicited paper or electronic mail as a result of sending DH any personal information. No personal information will be passed on to third parties for commercial purposes.

When we ask you for personal information, we promise we will:

- only ask for what we need, and not collect too much or irrelevant information;
- ensure you know why we need it;
- protect it and insofar as is possible, make sure nobody has access to it who shouldn't;
- ensure you know what choice you have about giving us information;
- make sure we don't keep it longer than necessary; and
- only use your information for the purposes you have authorised.

We ask that you:

- provide us with accurate information; and
- inform us as soon as possible of any changes or if you notice mistakes in the information we hold about you.

If you apply for a post, we will share some of the information you provide with the members of the selection panel for the post to which you applying, so that your application form and CV can be assessed.

Panel members are identified in the section below on "How we will handle your application". The 'monitoring information' you provide will not be used in the selection process and will therefore not be shared with the selection panel assessing your application at this stage.

## **How we will handle your Application**

We will deal with your application as quickly as possible and will advise you of the likely timetable at each stage. After the closing date for applications:

- your application and CV will be assessed to see whether you have the expertise required at the appropriate level for the post for which you have applied. We will rely on only the information you provide on your application form and CV to assess whether you have the experience required. Please ensure that you provide evidence to support how you meet all of the essential criteria;
- the selection panel will be chaired by Ms Sue Harris, MHRA and will also comprise Professor Philip Routledge, Chair of HMAc and Ms Hilary Randall, an External Panel Member;

- if you are invited to interview but are unable to attend on the set date then an alternative date can only be offered at the discretion of the panel;
- your application may be “long-listed”, subject to the volume of applications received, before it is passed to the shortlisting panel for consideration. You should be aware that in this situation, your application might not be considered in full by all of the panel;
- we anticipate that by late February 2013 the panel will have decided who will be invited for interview;
- the panel will select the people who have demonstrated that they best meet the essential criteria;
- we will write to let you know whether or not you have been invited to be interviewed. It is our intention that interviews will take place in a central London location;
- please note that due to the volume of applications we receive we are unable to provide feedback to those not shortlisted for interview;
- if invited to interview, the panel will question you about your experience and expertise and ask specific questions to assess whether you meet the criteria set out for the post;
- candidates who the panel believe are ‘appointable’, will be recommended to the MHRA’s Senior Responsible Officer who will make the final decision. The Senior Responsible Officer may choose to meet with appointable candidates before making a decision. If he does, he will meet all candidates and in the presence of the panel chair or their nominated representative;
- if you are successful, you will receive a letter from the MHRA appointing you as a Member of HMAC; and
- if you are unsuccessful, you will be notified by the Appointments Team. The letter will provide the details of who you may approach for feedback on your application.

### **Queries**

For queries about your application, please contact Holly Wainwright on 0113 254 6135.

### **If you are not completely satisfied**

DH will aim to process all applications as quickly as possible and to treat all applicants with courtesy. If you have any complaints about the way your application has been handled, please contact Jacky Cooper in the Department of Health by emailing [Jacky.Cooper@dh.gsi.gov.uk](mailto:Jacky.Cooper@dh.gsi.gov.uk).