



Chair and Vice Chair of the Review Panel (RP)

Information pack for applicants

Closing date: 12 noon on 19 February 2013

Reference no: EC12-33

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Chair and Vice Chair of the Review Panel (RP)

Overview

The roles

The Chair will provide strong and effective leadership of the Review Panel in the fulfilment of its remit.

In the absence of the Chair the Vice Chair will carry out this role.

Candidates for either post will need to be legally qualified with at least five years post-qualification experience and will need to demonstrate experience of committee and judicial work.

For further information on the role of the Chair and Vice Chair see **Annex A**.

The Review Panel

Following the 2010 Cabinet Office Public Bodies review the Review Panel was created as an MHRA Expert Committee by combining the functions of the Regulation of Medicine Review Panel (formerly known as 'Persons Appointed'), the Independent Review Panel on the Classification of Borderline Products and the Independent Review Panel on the Advertising of Medicines to form a single combined review panel which performs statutory and non-statutory reviews of proposals, decisions and provisional decisions taken by the MHRA on behalf of the licensing authority, the UK Health Ministers.

For further information on the role of the RP 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

The Chair will receive remuneration of £325 per meeting. The Vice Chair will receive remuneration of £200 per meeting other than when chairing a meeting, in which case he or she will then receive the Chair rate for that meeting.

Time commitment

Approximately six meetings per year.

Tenure of office

The Chair will be appointed for a three year term and the Vice Chair for a two year term.

Accountability

Both the Chair and Vice Chair are appointed by the Medicines and Healthcare products Regulatory Agency (MHRA)'s Senior Responsible Officer (the Chair) 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 the Review Panel and its Chair and Vice Chair please contact:

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

Please quote reference E12-33 on all correspondence.

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

Appointment of the Chair and Vice Chair

Role and responsibilities of the Chair

The Chair will provide strong and effective leadership of the RP in the fulfilment of its remit and in addition will:

- determine the appropriate composition of the RP for each case, choosing members from a multi-disciplinary pool of RP members based on the nature of the hearing;
- ensure that new RP members are briefed upon appointment to the multi-disciplinary pool of RP members;
- determine the procedure at each RP hearing;
- attend and chair each RP hearing;
- ensure that RP proceedings run smoothly and efficiently in order that its business is completed in a timely way;
- hear and consider the representations of the applicant and MHRA (together with other RP members);
- lead discussions amongst the RP members;
- consider, comment and contribute to RP discussions by drawing on individual expertise and judgement;
- provide a report to the MHRA which sets out the findings of the RP, to include a summary of the discussions, the outcome of those discussions and the recommendation(s) of the RP;
- conduct annual appraisals of RP members' performance;
- provide an annual report on the activities of the RP to the MHRA.

Role and responsibilities of the Vice Chair

In the absence of the Chair the Vice Chair will provide strong and effective leadership of the RP in the fulfilment of its remit and in addition will:

- determine the appropriate composition of the RP for the particular case, choosing members from a multi-disciplinary pool of RP members based on the nature of the hearing;
- determine the procedure at the RP hearing;
- ensure that RP proceedings run smoothly and efficiently in order that its business is completed in a timely way;
- hear and consider the representations of the applicant and MHRA (together with other RP members);
- lead discussions amongst the RP members;
- consider, comment and contribute to RP discussions by drawing on individual expertise and judgement;
- provide a report to the MHRA which sets out the findings of the RP, to include a summary of the discussions, the outcome of those discussions and the recommendation(s) of the RP;

Qualities required for both roles

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

- Legally qualified with a minimum of 5 years post-qualification experience.
- Judicial experience, experience of committee work at a national level or equivalent.
- Act as a skilled communicator and ability to demonstrate excellent interpersonal skills.
- Excellent written skills.
- Ability to work both independently and as part of a multi disciplinary team.
- Ability to work to tight deadlines.
- Attention to detail and accuracy.
- Ability to develop a good understanding of the UK and EU medicines regulatory scheme, including the Human Medicines Regulations 2012.

- Have no interests of a financial nature in the pharmaceutical industry (or be prepared to relinquish such interests on appointment).

Desirable criteria

- Experience in the UK and EU medicines regulatory fields.
- A working familiarity with the Human Medicines Regulations 2012.
- Previous experience of chairing a statutory or non-statutory review panel, national committee or similar.

Remuneration

- The Chair will receive remuneration of £325 per meeting. The Vice Chair will receive remuneration of £200 per meeting other than when chairing a meeting and will then receive the Chair rate for that 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 RP 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 six meetings per year.

Tenure of office

The Chair will be appointed for a three year term and the Vice Chair for a two year term.

Accountability

Both the Chair and Vice Chair 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 Chair or Vice Chair. Conflicts may relate to any relevant business interests, positions of authority or other connections with organisations relevant to the business of the RP.

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 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.

Review Panel role and responsibilities

The RP was created by combining the functions of the Regulation of Medicine Review Panel (formerly known as 'Persons Appointed'), the Independent Review Panel on the Classification of Borderline Products and the Independent Review Panel on the Advertising of Medicines to form a single combined Review Panel which performs statutory and non-statutory reviews of proposals, decisions and provisional decisions taken by the MHRA on behalf of the licensing authority, the UK Health Ministers.

The RP's terms of reference are:

- To perform the functions of "the reviewers" under regulations 162 and 163 of the Human Medicines Regulations 2012 (the Regulations) in relation to provisional determinations made by the MHRA, on behalf of the licensing authority, that a product is a medicinal product under regulation 159 of the Regulations.
- To perform the functions of "the reviewers" under Schedule 5 to the Regulations in relation to decisions or proposals of the MHRA, taken on behalf of the licensing authority, to (a) suspend, vary or revoke a manufacturer's or wholesale dealing licence under regulation 26 of the Regulations; (b) to grant, renew, revoke, vary or suspend a UK marketing authorisation, certificate of registration or traditional herbal under paragraphs 10 or 12 of Schedule 11 to the Regulations; (c) to refuse or grant in terms outside the terms of application a variation application under paragraph 22 of Schedule 11 to the Regulations; and (d) to refer an applicant to the Committee on Herbal Medicinal Products under paragraph 29 of Schedule 11 to the Regulations.
- To consider any written and/or oral representations made by a person or body notified under regulation 305 of the Regulations that the MHRA are minded to make a determination that that their advertisement is incompatible with the prohibitions; and/or to advise the MHRA prior to their making a final determination under regulation 306 of the Regulations.

Making an application

Overview

The appointment of the Chair and Vice Chair of the RP 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 and searching for the vacancy E12-33.

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.gov.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 Mr Richard Woodfield, MHRA and will also comprise Mr John Taylor, MHRA and Ms Hilary Randall as 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. If there is a strong field of candidates the panel may then look at who in addition meets any desirable criteria for the role in order to differentiate between those who would otherwise be of similar merit;
- 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 Senior Responsible Officer who will make the final decision. The MHRA 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 Senior Responsible Officer appointing you as either the Chair or Vice Chair of the Review Panel; 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