Chair of the Commission on Human Medicines

Information pack for applicants

Closing date: **12 noon on 4 December 2012**

Reference no: **A12-29**

Regulated by
The Commissioner for
Public Appointments

Contents

Chair of the Commission on Human Medicines

Overview

The role

The Chair will provide leadership to the Commission and its members to ensure that it provides the best possible advice on this critical area within the terms of the CHM.

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

The Commission on Human Medicines

The Commission on Human Medicines principal tasks are to advise the Licensing Authority (the UK Health Ministers) (LA) and its executive arm, the Medicines and Healthcare products Regulatory Agency (MHRA), on matters relating to human medicinal products including the licensing of medicines that are safe, efficacious and of good quality.

For further information on the role of the Commission on Human Medicines see **Annex B**.

Indicative timetable

Advert:	Monday 19 November 2012
Closing date:	12 noon on 4 December 2012 at 12 noon
Shortlisting complete:	mid December
Interviews held:	mid December
Appointment start date:	TBC

Remuneration

The Chair will be paid £500 for preparation / attendance per CHM meeting.

Time commitment

Approximately 30 days a year including 11 meetings.

Tenure of office

The Secretary of State for Health determines the length of appointments, which will be for up to a maximum of four years.

Accountability

The Chair is appointed by the Secretary of State and will be accountable to the Secretary of State via a senior Departmental official for carrying out their duties as Chair 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 CHM and its Chair please contact:

Leslie Whitbread
Tel: 0203 080 6451
Email: leslie.whitbread@mhra.gsi.gov.uk

Please quote reference A12-29 on all correspondence.

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

Annex A

Appointment of the Chair

Role and responsibilities of the Chair

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

In particular, the Chair will:

- grasp the Commission's full range of work relating to medicines which will include both national eg dealing with appeals from companies against the provisional advice of the Commission and European processes;
- capture and explore all the views of the Commission;
- ensure outcomes of discussion are clearly identified;
- ensure that the minutes of meetings, produced by the Secretariat, accurately record the decisions taken and advice given;
- represent the views of the Commission to the Chief Medical Officer and to Ministers;
- deal with the media;
- ensure that new Commissioners are briefed when appointed;
- conduct annual appraisals of Commissioners' performance; and
- advise the Medicines and Healthcare products Regulatory Agency on urgent ad hoc issues relating to medicines within the remit of the Commission outside the scheduled meetings as necessary.

Qualities required for the role of Chair

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

The successful candidate will:

- be medically qualified and recognised by peers as a leader in their field, eg by national academies and Royal Colleges;
- have previous or current experience of high-level committee membership, in areas similar to that of the Commission which will include revelant medical, scientific and public health aspects
- be a skilled communicator;

- have experience in the evaluation of benefit:risk of medicines;

- be able to assimilate complex scientific information at short notice; and provide formal and informal advice to Ministers and the Medicines and Healthcare products Regulatory Agency between meetings when required;

- should be prepared to relinquish all personal and non personal interests of a financial nature in the pharmaceutical industry.

Desirable criteria

- possess or develop a working knowledge and understanding of the UK/European medicines regulatory procedures;

- consider, comment and contribute by drawing on their individual expertise and judgement, as appropriate, on all agenda items and to assist the Commission to frame clear and unequivocal advice to Ministers in accordance with the Commission'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; and should be able and prepared to contribute actively to the range of work of the Commission;

- contribute to and ensure that the Commission'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.

Remuneration

- The Chair will be paid £500 for preparation / attendance per meeting.

- Remuneration is taxable, and subject to National Insurance contributions, both of which will be deducted at source under PAYE before you are paid.

- Those appointed will also be eligible to claim allowances, at rates set centrally, for travel and subsistence costs necessarily incurred on CHM 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 30 days a year including 11 meetings.

Tenure of office

The Secretary of State determines the length of appointments, which will be for up to a maximum of four years.

Accountability

The Chair is appointed by the Secretary of State and will be accountable to the Secretary of State via a senior Departmental official for carrying out their duties as Chair 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. Conflicts may relate to any relevant business interests, positions of authority or other connections with organisations relevant to the business of the CHM.

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 Senior Responsible Officer, to whom you will be accountable for your performance.

Standards in public life

You will be expected to demonstrate high standards of corporate and personal conduct. All successful candidates will be asked to subscribe to the *Code of Conduct for Board Members of Public Bodies,* you can access this document at: http://www.bl.uk/aboutus/governance/blboard/Board%20Code%20of%20Practice%202011.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.

Annex B

CHM role and responsibilities

The functions of the CHM are:

- to advise Ministers on matters relating to human medicinal products (except those that fall under the remit of Advisory Board on the Registration of Homeopathic Products (ABRHP) and Herbal Medicines Advisory Committee (HMAC) including giving advice in relation to the safety, quality and efficacy of human medicinal products, where either the CHM think it appropriate or where it is asked to do so;

- to advise the Licensing Authority (LA) where the LA has a duty to consult the CHM or where the LA chooses to consult the CHM;

- to consider representations made in relation to the CHM's advice (either in writing or at a hearing) by an applicant or by a licence or Marketing Authorisation (MA) holder; and

- to promote the collection and investigation of information relating to adverse reactions for human medicines (except for those products that fall within the remit of ABRHP or HMAC) for the purposes of enabling such advice to be given.

Background on some aspects of the CHM's work

Regulation of Medicines

MA and product licence applications for new active substances may be referred to the CHM.

The LA (UK Health Ministers) acting through the Medicines and Healthcare products Regulatory Agency (MHRA) authorises new products and generic products to be made available on the UK market and contributes to decisions on authorising products for use throughout the European Union. Such applications are reviewed by the Agency's professional staff, and if they are considered to be satisfactory, they will generally be granted without referral to the CHM.

The LA cannot **refuse** an application for an MA without seeking the CHM's advice. In addition the LA receives many applications for changes to the MAs of existing medicines. There is no requirement to consult the CHM before a variation application is refused, but the CHM will generally be consulted when an application is for a major change to the licensed indications of a product such as an entirely new indication, or a change from second-line to first-line usage, or a change with major public health implications. For some variation applications (where the CHM has been consulted or not) the applicant will be entitled to a hearing before the CHM if his application is refused.

If the CHM's provisional view is that it may have to advise the LA to refuse an application (other than a variation application), or to grant it otherwise in accordance with the application, the CHM communicates this view to the applicant, who then has an opportunity to make written or oral representation to the CHM.

Pharmacovigilance

The CHM is also responsible for promoting the collection and investigation of information relating to adverse reactions (except for products that are the remit of ABRHP and HMAC). The MHRA is responsible for the day to day monitoring of drug safety and for recommendations on actions to improve the safety of medicines including responsibility for the “yellow card” scheme.

Information from a wide variety of sources is used to monitor the safety of authorised medicines. It is the responsibility of the MHRA to identify signals of possible drug safety hazards from this information, to investigate these and, where necessary, conduct risk benefit analyses to determine whether any action is necessary to improve the safety of medicines. Issues of drug safety may also be brought to the attention of the MHRA from many sources and these are similarly investigated and acted upon.

The LA seeks the CHM's advice on issues where safety hazards have been identified.

Information obtained from post-marketing experience may lead to the need for the MA to be updated in variety of ways. Much of this is done by voluntary agreement with the pharmaceutical company concerned. Where this is not obtained, formal action may be taken either through the European scientific committee - the Committee on Human Medicinal Products (CHMP) or, if the matter is not of community interest, under the UK MA Regulations. In such cases, the CHM will be asked to advise the LA on variation, suspension or revocation of the MA. The company will be given the opportunity to make representations to the CHM before regulatory action is taken. In the case of a major drug safety hazard the MA may be suspended or an urgent safety restriction issued with immediate effect by the LA. The company will be given similar rights to make representations before any final advice is given or permanent action taken.

Change of legal status

Another important issue on which the CHM may be consulted is proposed changes to a drug's legal status. All authorised medicines fall into one of three categories: POM (Prescription Only Medicines), P (Pharmacy) or GSL (General Sales List).

Where a change is advised by the CHM, wider interests may be consulted (e.g. professional bodies, consumer groups etc.) and their responses may be presented to the CHM for consideration and advice to the LA.

European authorisation procedures

The first European Directive on pharmaceuticals was published in 1965. The twin aims of European medicines legislation are harmonising the terms in which the products are authorised in the EU in support of Single Market objectives and public health protection. There are currently three European authorisation procedures, the Centralised, Mutual Recognition & Decentralised procedures. CHM Commissioners will regularly be asked to review products submitted under these procedures that have very short time lines for comments.

The Centralised Procedure applies to a range of products identified in European legislation. At present, it applies to biotechnology products, products containing new active substances and any other application considered to be of significant community interest. All new therapies for use in the treatment of neuro-degenerative disorders, HIV/AIDS, cancer and diabetes are required to go through the Centralised procedure. A successful application under this procedure results in a single authorisation which is valid throughout the EU. The MA is granted by the European Commission and managed by the European Medicines Agency (EMA). Safety of products in use remains a Commissioner State responsibility.

The EMA is situated in London at Canary Wharf. It manages the Centralised Procedure for MAs for both human and veterinary products. The staff of the EMA do not carry out assessments but manage applications through the procedure, provide the Secretariat for the CHMP (see below) and assist in preparing documents for release to the industry and the public. The scientific assessment of applications is undertaken by Commissioner States‟ experts when that Commissioner State is nominated as either the “rapporteur” or “co-rapporteur”.

CHMP

The CHMP provides the scientific input into the authorisation process. It is composed of a Chair and one delegate per Member State, with a nominated alternate per Member State plus up to five co-opted Members (who need not be representatives of Commissioner States), a representative from Norway and one from Iceland.

The CHMP meets once a month at the EMA. Each meeting lasts for up to four days. Delegates of the CHMP are supported by experts from the national authorities and independent experts chosen for expertise in the applications under discussion. Members of the CHM and its Expert Advisory Groups (EAGs) will be asked to attend CHMP meetings when their expertise would be helpful.

The CHMP has a number of Committees/Working Parties. The major ones are: Biotechnology, Quality, Safety (pre-clinical), Efficacy, Pharmacovigilance, Herbal, Orphan Medicinal Products, Paediatric Medicines and Invented Names Review. A key task of the committees/working parties is to prepare guidelines for the pharmaceutical industry to use in the preparation of their applications. Commissioners may be asked to comment so as to assist in the preparation of guidelines in their field of expertise. The CHMP also has Scientific Advisory Groups (SAGs), similar to the EAGs, and may call expert working groups to consider specific issues. Members of the CHM/EAGs are quite often required to attend. Currently, five Commissioners Chair SAGs.

Centralised Procedure

For applications under the Centralised Procedure, the CHMP appoints a rapporteur and co-rapporteur from among the Member States. All Member States are eligible. The UK is one of the leading Member States for rapporteurship. When the UK acts as rapporteur or co-rapporteur, the CHM will normally be asked to review the full assessment as they will for a National application. In the case of routine non rapporteur applications the LA (acting through MHRA) will normally seek written comments from Members of the CHM/EAGs/external panel depending on the expertise required. This entails reading the assessment reports (summary of the company data) of the rapporteur and providing views that form the basis of the United Kingdom position. In certain circumstances in non rapporteur cases, the MHRA may decide to seek the view of the CHM. In these situations the MHRA will also provide a limited assessment to accompany the rapporteurs reports.

The Mutual Recognition and Decentralised Procedures

The Decentralised and Mutual Recognition Procedures are European authorisation procedures based on the principle of recognition of the assessment by the Reference Member State (RMS). These remain national authorisations, but have harmonised product information.

Mutual Recognition Procedure

In the case of the Mutual recognition procedure, the Member State chosen as RMS has already issued a national marketing authorisation. The RMS's assessment report then forms the basis for requesting the other Concerned Member States (CMS) mutual recognition of the MA (including the Summary of Product Characteristics (SPC), package leaflet and labelling text), unless they have objections on the grounds of a potential serious risk to public health. The time allowed for recognising another Member State's MA is 90 days.

Decentralised Procedure

The Decentralised procedure may be used to obtain a MA in several Member States when the applicant does not yet have a MA in any country. The applicant requests one Member State to be the RMS in the procedure. After 70 days the RMS circulates a preliminary assessment report and comments from CMS are due by Day 100 of the procedure. On Day 120 of the assessment procedure, the RMS circulates the draft assessment report incorporating the applicant's response to questions raised at Day 70 and Day 100, and including comments on the Summary of Product Characteristics, package leaflet and labelling texts. There is then a Mutual Recognition Procedure during the next 90 days of the procedure, in which the CMS generally adopt the RMS's assessment, unless they have important objections on the grounds of a potential serious risk to public health.

Post-authorisation

When an MA has been granted through the Mutual Recognition or Decentralised Procedure, all variations and changes to the product literature are carried out in the Mutual Recognition process. This means that the product literature will remain harmonised throughout the EU for each individual mutually recognised product.

Expert Advisory Groups (EAGs)

In its work the CHM is supported by 12 EAGs covering the following therapeutic areas

- Anti Infectives, HIV & Hepatology
- Biologicals & Vaccines
- Cardiovascular, Diabetes, Renal, Respiratory & Allergy
- Chemistry, Pharmacy & Standards
- Clinical Trials
- Gasterenology, Rheutamology, Immunology & Dermatology
- Medicines for Women's Health
- Neurology, Pain Management & Psychiatry
- Oncology & Haematology
- Paediatric Medicines
- Patient & Public Engagement
- Pharmacovigilance

All the EAGs are chaired by Commissioners with the exception of three. In addition ad hoc groups are established to look at specific issues and these will be chaired by Commissioners.

Annex C

Making an application

Overview

The appointment of Chair of CHM is a Secretary of State appointment. 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 Secretary of State on candidates they believe are 'appointable'. Taking into account feedback from the panel, the Secretary of State 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 A12-29.

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 3E44)
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 4 December 2012**.

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, however, the Commissioner for Public Appointments requires that selection panels review the political activity response at the interview stage. This in no way acts as a bar to appointment.

The Commissioner for Public Appointments regulates and monitors appointments to public bodies to ensure procedures are fair. The Department of Health is required by the Commissioner for Public Appointments to retain information about the people who apply for public appointments within his remit, and make this information available to him for audit purposes, if requested to do so. Information you provide in your application may therefore be made available to the Commissioner for Public Appointments and the Commissioner’s auditors on a confidential basis in order to help fulfil either the Commissioner’s formal complaints investigation role or for audit purposes.

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 relevant criteria;

- the selection panel will be chaired by Sara Nathan, Public Appointments Assessor and will also comprise Dr Ian Hudson, Director of Licensing, Department of Health, Sir Gordon Duff, Incoming MHRA Chair, Tim Baxter, DH Deputy Director of the Public Health Development Unit and 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 early December the panel will have decided who will be invited for interview mid December;

- 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 Secretary of State who will make the final decision. The Secretary of State 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 Secretary of State appointing you as the Chair of the CHM; 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.

Regulation by the Commissioner for Public Appointments

We noted above the role of The Commissioner for Public Appointments regarding audit. The Commissioner regulates and monitors appointments to public bodies to ensure procedures are fair. More information about the role of the Commissioner and his Code of Practice is available from www.publicappointmentscommissioner.org.

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.

If after receiving a comprehensive response from the Department you are still concerned, you can write to the Commissioner for Public Appointments. Please contact:

The Commissioner for Public Appointments
1 Horse Guards Road
London SW1A 2HQ

Tel: 0207 271 0849
Email: enquiries@publicappointmentscommissioner.org