



Department
of Health &
Social Care



MHRA
Regulating Medicines and Medical Devices

Chair of the Medicines and Healthcare products Regulatory Agency

Information pack for applicants

Closing date: midday on 17th March 2020

Reference no: VAC-1679



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Contents

Section 1 – The Role	2
1.1 Role and Responsibilities of the Chair of the Medicines and Healthcare products Regulatory Agency	2
1.2 The Medicines and Healthcare products Regulatory Agency’s role and responsibilities	5
Section 2: How to Apply	8
2.1 Making an application	8
2.2 The Selection Process	12
2.3 Eligibility Criteria	15
2.4 How we will manage your personal information	16

Section 1 – The Role

1.1 Role and Responsibilities of the Chair of the Medicines and Healthcare products Regulatory Agency

Introduction

Ministers are seeking to make an appointment to the Medicines and Healthcare products Regulatory Agency (MHRA).

Role and Responsibilities of the Chair

The Chair of the MHRA is accountable to the Secretary of State for Health and Social Care and will:

- Provide strong leadership, challenge and direction to the organisation, encouraging and enabling the MHRA to be a first-class regulator of medicines and medical devices, building on its international status and leading the Agency through the changes to come now we have left the European Union.
- In partnership with the Executive Team and Board members, ensure that the MHRA drives a major multi-year operational transformation programme, within the agreed financial envelope, delivering significant changes to fundamentally reshape the way the Agency operates, including driving efficiencies throughout the business.
- Ensure high standards of governance and effectiveness, encourage and enabling non-executive directors to make a full contribution to the Board's affairs, making best use of their varied skills and diverse backgrounds, and advising the Department of Health and Social Care on their performance.
- In partnership with the Chief Executive, set the tone for excellent working relationships between the three centres that comprise the MHRA, as well as between the MHRA and key stakeholders. Ensure that policy and operational decisions reflect the needs and views of stakeholders, including patients, the public, NHS and industry to deliver confidence in the work of the Agency during challenging times.
- Progress the Agency's innovation agenda creatively and effectively, seeking new opportunities and delivering on the Agency's commitments to support the Government's Strategy for UK Life Sciences.

Qualities required for the role of the Chair

The Department of Health and Social Care values and promotes diversity and encourages applications from all sections of the community. The boards of public bodies should reflect the population they are there to serve. Boards also benefit from fresh perspectives, and we are always keen to encourage candidates with private sector experience to consider applying for our roles.

Essential Criteria

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.

- A career record of achievements in the life sciences sector, or transferable experience from an alternative regulatory sector, of scale and relevance consistent with being the Chair of MHRA.
- Ability to support innovation in the sector while safeguarding the independence and rigour of MHRA in protecting public health.
- Exemplary governance, organisational and transformational leadership skills, able to lead the board of a significant national public body through substantial change within a large, complex system.
- Excellent communicator, able to gain the confidence of and build successful alliances with a range of stakeholders, both domestic and international, and including Ministers.

Remuneration

- Remuneration is £63,000 per annum.
- Remuneration is taxable, and subject to National Insurance contributions, both of which will be deducted at source under PAYE before you are paid. Remuneration is not pensionable.
- You may claim travel and subsistence expenses, which are properly and necessarily incurred in carrying out your role and responsibilities as the Chair of the MHRA, in line with travel and subsistence policy and rates for the MHRA. A copy of the policy and rates can be obtained from the MHRA.

Time commitment

2 to 3 days per week

Board meetings dates are generally arranged for the third Monday of every month

Location

London

Tenure of office

Ministers determine that the length of the appointment will be up to 3 years.

Accountability

This Chair is appointed by the Secretary of State and is accountable to the Secretary of State via a senior Departmental official for carrying out their duties and for their performance.

For further information regarding the role of the MHRA and the role of the Chair please contact:

Elizabeth Woodeson via Ty Vuong:

Email: Ty.Vuong1@dhsc.gov.uk

1.2 The Medicines and Healthcare products Regulatory Agency's role and responsibilities

“This is a pivotal time in the Agency’s history and we are in the process of organisational transformation to enhance our vital role in the safeguarding of public health. During the coming three years the Chair will play a key role as the Agency delivers an ambitious business change programme which will help maintain the UK as a global centre of excellence in medical science, in the best interests of patients and the public.”

Dr June Raine, CEO of MHRA

The Medicines and Healthcare products Regulatory Agency (MHRA) regulates medicines, medical devices and blood components for transfusion in the UK. It is an executive agency, sponsored by the Department of Health and Social Care. The Agency employs more than 1,300 people and has facilities in London, York and South Mimms in Hertfordshire.

Recognised globally as an authority in its field, the agency plays a leading role in protecting and improving public health and supports innovation through scientific research and development.

The agency has three centres:

- The Clinical Practice Research Datalink (CPRD), a data research service that aims to improve public health by using anonymised NHS clinical data.
- The National Institute for Biological Standards and Control (NIBSC), a global leader in the standardisation and control of biological medicines.
- The Medicines and Healthcare products Regulatory Agency (MHRA), the UK’s regulator of medicines, medical devices and blood components for transfusion, responsible for ensuring their safety, quality and effectiveness.

The agency is responsible for:

- Ensuring that medicines, medical devices and blood components for transfusion meet applicable standards of safety, quality and efficacy.
- Ensuring that the supply chain for medicines, medical devices and blood components is safe and secure.
- Promoting international standardisation and harmonisation to assure the effectiveness and safety of biological medicines.
- Helping to educate the public and healthcare professionals about the risks and benefits of medicines, medical devices and blood components, leading to safer and more effective use.
- Supporting innovation and research and development that’s beneficial to public health.
- Influencing UK and international regulatory frameworks so that they’re risk-proportionate and effective at protecting public health.

MHRA's current priorities

- Lead development of the UK's approach to regulation of medicines and medical devices, following the UK's departure from the European Union, strengthening MHRA's global role and influence.
- Drive an ambitious transformation plan throughout the Agency to deliver a more flexible and efficient organisation, using state-of-art digital technology, able to respond effectively to market and customer requirements.
- Develop regulation which supports transformational innovation and the safe manufacture, sale and supply of medicines and medical devices.
- Support the government's growth agenda through the life science strategy and sector deal commitments, which include early access to medicines schemes and the adaptive licensing pilot.
- Contribute to system wide response to the Independent Medicines & Medical Devices Safety (IMMDS) review, including a fundamental review of MHRA's engagement with patients and the public to improve public health and patient safety.

The MHRA Board

The MHRA operates a unitary Board, the role of which is to provide strategic advice on the running of the Agency, ensuring that effective arrangements are in place to:

- Provide assurance and review the controls needed for effective risk management, governance and internal control.
- Demonstrate sound financial management and good value for money.
- Ensure that the Agency has the capability to deliver.

Specifically, the Board is collectively responsible for the following:

- Agreeing the strategic aims and objectives of the Agency, consistent with its overall strategic direction and within the policy and resources framework determined by the Secretary of State.
- Endorsing the Agency's recommendations to Ministers on the Agency's key financial and performance targets and the Agency's annual business plan and five-year corporate plan.
- Agreeing the content of the Agency's annual report to be proposed to Ministers.
- Advising on and monitoring:
 - The implementation of strategies to ensure that the regulatory systems for medicines and medical devices are effective and robust, given developments in science and technology, at a UK and international level;
 - The implementation of strategies for increasing public knowledge and understanding about the safe use of medicines and medical devices
 - The service provided to the manufacturers of medicines and medical devices, to health and social care professionals and to the general public

- The steps taken by the Agency to protect the interests of the public by ensuring that medicines meet appropriate standards of safety, quality and efficacy and that medical devices meet appropriate standards of safety, quality and performance; and
- The steps taken by the Agency to support innovation and growth and the impact these have had on public health.

Useful information:

[Medicines and Healthcare products Regulatory Agency \(MHRA\)](#)

[National Institute for Biological Standards and Control \(NIBSC\)](#)

[Clinical Practice Research Datalink \(CPRD\)](#)

[2018-19 Annual Report and Accounts](#)

[2019-20 Business Plan](#)

[2018-23 Corporate Plan](#)

[The Life Sciences Sector Deals](#)

[The Independent Medicines & Medical Devices Safety \(IMMDS\) Review](#)

Section 2: How to Apply

2.1 Making an application

Thank you for your interest in the appointment of the Chair to the MHRA.

To make an application please email your CV, a supporting letter and completed monitoring forms to:

appointments.team@dhsc.gov.uk – please quote **VAC-1679** in the subject field.

If you are unable to apply by email you may send your application by post to:

Kuldeep Kanda Department of Health and Social Care, Room 1N09, Quarry House, Quarry Hill, Leeds, LS2 7UE

Applications must be received by midday on 17th March 2020.

In making an application please note the following:

Supporting letter

The supporting letter is your opportunity to demonstrate how you meet each of the criteria set out in the person specification. It will benefit the Advisory Assessment Panel if you can be clear which specific evidence you provide relates to which criteria. Providing separate paragraphs in relation to each criterion is common practice. Please write all acronyms in full first.

Please ensure your full name, the role to which you are applying and the corresponding reference number for the post are clearly noted at the top of your letter.

Please limit your letter to two pages, and type or write clearly in black ink.

Conflicts of interest

If you have any business or personal interests that might be relevant to the work of the MHRA, and which could lead to a real or perceived conflict of interest if you were to be appointed, please provide details in your supporting letter.

If appointed, you will also be required to declare these interests on appointment and they will be entered on a register which is available to the public.

Standards in public life and ensuring public confidence

Given the nature of public appointments, it is important that those appointed as members of public bodies maintain the confidence of the public and Government. If there are any issues in your personal or professional history (including any convictions or bankruptcy) that could, if you were appointed, be misconstrued, cause embarrassment to Ministers or MHRA or cause public confidence in the appointment to be jeopardised, it is important that you bring them to the attention of the Assessment Panel and provide details of the issue/s in your Supporting letter. In considering whether you wish to declare any issues, you should also reflect on any public statements you have made, including through social media and blogs. Due Diligence may be carried out on any publicly available information and shared with the Advisory Assessment Panel.

The panel may explore any issues you declare with you before they make a recommendation on the appointment.

Failure to disclose such information could result in an appointment being terminated, as those who hold public appointments are expected to demonstrate the highest standards of corporate and personal conduct and are required to subscribe to the Code of Conduct for Board Members of Public Bodies, as part of agreeing to the terms and conditions of appointment. You can access this document at:

<https://www.gov.uk/government/publications/board-members-of-public-bodies-code-of-conduct>

There are also circumstances in which individuals may not be considered for appointment, due to them not meeting certain eligibility criteria for appointment. For further information, please refer to **Section 2.3: Eligibility Criteria**

If you wish to discuss any queries on conflicts, please see the contacts section.

CV

Please ensure your CV includes:

- Your full name, title, home address, personal contact telephone numbers (land line and mobile), personal email address and details of any twitter accounts and LinkedIn accounts including your twitter handle/username.
- Similar contact details for two referees who will support your application. One referee should be the person to whom you are/were accountable in your current/most recent appointment or position of employment. Please indicate the relationship of each referee to you. References will be requested for short-listed candidates prior to interview.

- Brief details of your current or most recent post and the dates you occupied this role. Please identify any past or present Ministerial appointments.

Monitoring form

Please complete the monitoring form. Diversity monitoring information will not be seen by the Advisory Assessment Panel assessing your application.

Political activity information is primarily for monitoring purposes only, however if you are shortlisted for interview, this information will be shared with the selection panel. The reason for this is that it is appreciated that such activities may have given you relevant skills, including experience gained from committee work, collective decision-making, resolving conflict and public speaking. If you have had such experience and you consider it relevant to your application for this post, you should also take the opportunity to include it separately in your supporting statement. If possible, you should not, however, identify the relevant political party in your statement.

Guaranteed Interview Scheme

The Department of Health and Social Care operates a Guaranteed Interview Scheme (GIS) for disabled people. The Equality Act 2010 defines a person as disabled if they have a physical or mental impairment and the impairment has a substantial and long-term adverse effect on their ability to carry out normal day to day activities. Under the GIS a disabled candidate will be selected for interview if they meet the essential criteria for the post.

If you wish to apply under the GIS please complete the GIS form and return it with your application.

All applications will be acknowledged by email after the closing date.

Contacts

For further information regarding the selection process, please contact

Kully Kanda

Appointments Team

Tel: 0113 2545929

Email: Kuldeep.Kanda@dhsc.gov.uk

For further information regarding the role of the MHRA and the role of the Chair please contact:

Elizabeth Woodeson via Ty Vuong:

Email: Ty.Vuong1@dhsc.gov.uk

Please quote reference **VAC-1679** on all correspondence.

If you choose to apply, we would like to thank you in advance for your time and effort in making an application.

2.2 The Selection Process

The Appointments Team will deal with your application as quickly as possible and will advise you of the likely timetable at each stage.

Timetable:

- Closing date: Midday on 17th March 2020
- Shortlisting complete: 9th April 2020
- Interviews held: 14th May 2020

The selection panel will be:

- Steve Oldfield, Commercial Director (panel chair)
- Elizabeth Woodeson, Director of Medicines and Pharmacy
- Sir John Bell as an Independent Panel Member

The Independent Panel Member is independent of both the Department of Health and Social Care and MHRA.

After the closing date for applications:

- The Department of Health and Social Care may commission a pre-assessment of candidate applications which would then be provided to the Panel for consideration and to inform the shortlisting process. By applying, you are agreeing to your application being shared with another party for pre-assessment. The pre-assessor and the panel are reliant on the information you provide in your CV and supporting letter to assess whether you have the skills and experience required. Please ensure that you provide evidence to support how you meet all the essential criteria. It is the responsibility of the panel to determine who it believes best meet the criteria for the role, and who will be invited to interview.
- Interviews will be held on 14th May 2020.
- The Advisory Assessment Panel will select for interview only the strongest applicants who it feels have demonstrated that they best meet the criteria set out in the person specification. However, if you have applied under the GIS and you meet all the essential criteria, then you will also be invited for interview.
- If you are invited to interview and if you are unable to attend on the set date, then an alternative date can only be offered at the discretion of the Advisory Assessment Panel.

- The Appointments Team will email to let you know whether you have been invited to be interviewed. It is our intention that interviews will take place in a central London location.
- If invited to interview, the Advisory Assessment Panel may invite you to make a brief presentation at the start of the interview and will go on to question you about your skills and experience, including asking specific questions to assess whether you meet the criteria set out for the post.
- The Advisory Assessment Panel will also explore with candidates any potential conflicts of interest or any other issues arising from candidate's personal and professional history which may impact on an appointment decision (see section 2.1 for further details).
- Candidates who the panel believe are 'appointable', will be recommended to Ministers who will make the final decision. Ministers may choose to meet with shortlisted candidates, before or after interview, before making a decision. Candidates should therefore be prepared for a short time gap between interview and a final appointment decision being made. Candidates who have been interviewed will be kept informed of progress.
- If you are successful, you will receive a letter from Ministers appointing you as the Chair of the MHRA, which will confirm the terms on which the appointment is offered.
- **Please note that due to the volume of applications that are received it is not possible to routinely provide feedback to those not shortlisted for interview.**
- If you apply under the GIS scheme and you are not shortlisted for interview, we can provide a summary of the assessment of your written application, if you choose to request feedback.
- If you are unsuccessful at interview, you will be notified by the Appointments Team. We appreciate it takes a lot of time and effort to apply for roles, and prepare for and attend an interview, and that feedback is a valuable part of the process. Following interviews, the letter which confirms the outcome of the appointment process will provide the details of who you may approach for feedback on your interview and application, if you so wish.
- For further information on how we will manage the personal information that you have provided to us through your application, see **Section 2.4**.

Queries

For queries about your application, please contact Kuldeep Kanda on kuldeep.kanda@dhsc.gov.uk

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: <https://www.gov.uk/government/publications/board-members-of-public-bodies-code-of-conduct>

Diversity and equality of opportunity

The Department of Health and Social Care values and promotes diversity and encourage applications from all sections of the community.

Governance Code on Public Appointments

The Governance Code on Public Appointments, published by the Cabinet Office, sets out the principles that should underpin all public appointments. The Governance Code can be found at <https://www.gov.uk/government/publications/governance-code-for-public-appointments>

If you are not completely satisfied

The Department of Health and Social Care 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 Sally Brough-Hirst in the Department of Health and Social Care by emailing Sally.Brough-Hirst@dhsc.gov.uk

2.3 Eligibility Criteria

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

1. Persons who have received a prison sentence or suspended sentence of 3 months or more in the last 5 years.
2. Persons who are the subject of a bankruptcy restrictions order or interim order, or a debt relief order or interim debt relief order under Schedule 4ZB to the Insolvency Act 1986.
3. Persons who have had an earlier term of appointment with a health service body terminated on the grounds:
 - That it was not conducive to the interests or good management of the body that the person should continue to hold office.
 - That the person failed to attend a meeting of the body on three consecutive occasions.
 - That the person failed to declare a pecuniary interest or withdraw from consideration of a matter in respect of which the person had a pecuniary interest.
 - Of misconduct or failure to carry out the person's duties.
4. Anyone who is under a disqualification order under the Company Directors Disqualification Act 1986; or
5. Anyone who has been removed from trusteeship of a charity.

Further advice about the Eligibility Criteria can be provided by contacting Kuldeep Kanda on 0113 254 6769.

2.4 How we will manage your personal information

Your personal information will be held in accordance with the Data Protection Act 2018. You will not receive unsolicited paper or electronic mail because of sending the Department of Health and Social Care 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.
- Only use your information for the purposes you have authorised.

We ask that you:

- Provide us with accurate information.
- 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 are applying, so that your CV and supporting letter can be assessed.

The diversity information you provide will not be used in the selection process and will therefore not be shared with the Advisory Assessment Panel assessing your application at any stage.

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