



# Non-Executive Directors of the Medicines and Healthcare products Regulatory Agency

Information pack for applicants

**Closing date: midday on 10 May 2021**

**Reference no: VAC-1715**



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# Section 1 – The Role

## 1.1 Introduction

Ministers are seeking to make up to four appointments to the board of the Medicines and Healthcare products Regulatory Agency.

“With the ongoing challenges of responding to the COVID-19 pandemic, Brexit and the Cumberlege Review, the MHRA is now at a pivotal point in its history of protecting and improving patient health through proportionate and progressive medical product regulation, whilst also enabling innovation and early patient access to new medical technologies in the UK with the involvement of patients and use of real-world data in our regulatory processes.

If you have the strategic insight, domain expertise and desire to make a difference to patient lives in this country and around the world, then we’d like to hear how you could help us achieve our ambitions.”

*Stephen Lightfoot, Chair of the Medicines and Healthcare products Regulatory Agency*

## 1.2 Role and Responsibilities of a Non-Executive Director

Non-Executive Directors (NEDs) are appointed to provide independent and constructive challenge to enable the Board to achieve its responsibilities. All NEDs must be independent of management and must allocate sufficient time to the Agency Board to discharge their responsibilities effectively. This includes ensuring that high standards of corporate governance are observed at all times and ensuring that the Agency operates in an open, accountable and responsive way.

As a NED, you will:

- Contribute to the development of the Agency’s strategic direction and strategic objectives, taking into account your own understanding of the external environment that could impact on the achievement of these objectives
- Contribute to the governance of the Agency by ensuring that independent oversight is maintained on the Agency’s operational effectiveness, patient engagement, risk management, financial efficiency and working relationship with key stakeholders
- Monitor the overall performance of the Agency and hold the Executive Committee to account for the delivery of the agreed strategic imperatives and business plan objectives
- Become an active and constructive member of at least one of the three MHRA Board Assurance Committees and take on at least one special interest role so that the board can benefit from independent, specialist expertise built outside the Agency
- Act as an ambassador for the Agency at all times and help connect the Agency with stakeholders in other organisations when appropriate. Individual NEDs may be asked

to represent the Agency in external meetings in some situations, but only with the prior agreement of both the Chair and the Chief Executive

- Identify any matters that may adversely affect the reputation or public trust in the Agency's work, through a broad understanding of the wider UK and international environment in which the Agency operates
- Act as a "critical friend" by providing independent counsel, support and constructive challenge to members of the Executive Committee without straying into the day-to-day management of the organisation.

## **Qualities required for the role of a NED**

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 record of achievement and an ability to operate effectively on the board of a significant national organisation, with the highest standards of personal propriety in relation to governance, accountability and conduct.
- Demonstrable interest in the work of the MHRA, and particularly in the development of new medical products and the role of regulation in enabling innovation.
- Excellent communication skills, sound judgement and demonstrable experience of strategic thinking, with the ability to scrutinise and challenge complex proposals constructively.

In addition, candidates should bring specific skills and experience in at least one of the following areas:

### **Expertise on Innovative Medicines – 2 NED roles**

- Candidates will have a medical or healthcare qualification and be considered by their peers to have specialist knowledge on the development and/or clinical use of innovative biological medicines, cell and gene therapies and/or companion diagnostics to deliver meaningful patient benefits.

### **Expertise on Digital Health and/or Medical Technologies – 2 NED roles**

- Candidates will have a track record of working on the development and clinical application of digital health, artificial intelligence, and/or innovative medical technologies to deliver meaningful patient benefits.

Other skills which would be highly desirable and valued by the Board include experience of innovative clinical trial design and delivery; patient safety, vigilance and risk management; patient involvement and engagement; and use of real-world data.

## Remuneration

- The NEDs are remunerated at the standard rate of £7,883 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 a NED of the MHRA, in line with travel and subsistence policy and rates for the agency. A copy of the policy and rates can be obtained from the MHRA

## Time commitment

Time commitment will be 2 to 3 days per month

## Location

London

Board meetings dates are generally arranged for the third Tuesday of every month. Dates of future meetings are available on MHRA's website.

## Tenure of office

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

## Accountability

Non-Executive Directors are appointed by the Secretary of State for Health and Social Care and are accountable to the Secretary of State via the Chair for carrying out their duties and for their performance.

## 1.3 Medicines and Healthcare products Regulatory Agency role and responsibilities

The Medicines and Healthcare products Regulatory Agency 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 1,200 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 an income of around £140 million, funded mainly from fees and sales of its services, with the remainder of funds coming from central government and research funding.

The Agency engages actively with other public, academic and commercial organisations in the wider health system, in addition to other international regulators.

The Agency has three centres:

- **MHRA Regulator**, which protects health and improves lives by ensuring that medicines and medical devices work and are acceptably safe; focusing on the core activities of product licensing, pharmacovigilance, inspection and enforcement.
- The **Clinical Practice Research Datalink (CPRD)**, which gives access to an unparalleled resource of anonymised patient data for conducting observational research and improving the efficiency of interventional research, across all areas of health, medicines and devices.
- The **National Institute for Biological Standards and Control (NIBSC)**, leaders in assuring the quality of biological medicines through product testing, developing standards and reference materials to facilitate the development of new medicines, and conducting world class scientific research.

### Current priorities

The Agency is undergoing a fundamental transformation of its organisation, strategic priorities and regulatory processes in response to the UK transition out of the EU, the findings of the Independent Medicines and Medical Devices Safety Review and the learnings from the response to the COVID-19 pandemic. Some of the current activities include:

- Developing regulation that is more supportive of safe innovation
- Supporting the government's growth agenda through the life science strategy, which includes early access to medicines schemes and the adaptive licensing pilot
- Introducing a combined reporting system for adverse incidents, medicines, medical devices, blood and counterfeit products under the established Yellow Card brand to ensure patient safety
- Working with partners across the UK and globally to prevent counterfeit and substandard products entering the supply chain
- Establishing a centre of excellence for advanced therapies, including stem cells, at NIBSC

- Increasing the volume of observational and interventional research, including clinical trials, using CPRD data
- Engaging and networking more with healthcare professionals, patients and the public, including by working jointly with others in the health and social care system.

## **The Board**

The strategic leadership and internal governance of the Agency is ensured by a Unitary Agency Board, which comprises of an equal number of Executive and Non-Executive Directors from a broad range of backgrounds, plus a Non-Executive Chair.

The Board is responsible for advising on the strategic direction of the Agency, ensuring that targets set out in the business plan and agreed with ministers are met. Its strategic priorities are ensuring patient safety, enabling healthcare access, building a dynamic organisation and delivering financial sustainability.

The Board is supported by three Assurance Committees chaired by a Non-Executive Director and these include the Audit & Risk Assurance Committee, Patient Safety & Engagement Assurance Committee and Organisational Development & Remuneration Committee.

Although it does not have involvement in any regulatory decisions affecting medical products, the Board supports the Chief Executive in the effective delivery of services and overall performance by providing leadership, developing strategy, advising on the delivery of policies, maintaining high standards of corporate governance, scrutinising performance and ensuring that controls are in place to manage risk.

## **Useful information:**

Medicines and Healthcare products Regulatory Agency (MHRA) - [Medicines and Healthcare products Regulatory Agency - GOV.UK \(www.gov.uk\)](http://www.gov.uk)

National Institute for Biological Standards and Control (NIBSC) - [NIBSC - Home](http://www.nibsc.ac.uk)

Clinical Practice Research Datalink (CPRD) - [Clinical Practice Research Datalink | CPRD](http://www.cprd.com)

2019-20 Annual Report and Accounts - [Medicines and Healthcare Products Regulatory Agency Annual Report and Accounts 2019 to 2020 - GOV.UK \(www.gov.uk\)](http://www.gov.uk)

2020-21 Business Plan - [Medicines and Healthcare products Regulatory Agency Business Plan 2020 to 2021 - GOV.UK \(www.gov.uk\)](http://www.gov.uk)

2018-23 Corporate Plan - [MHRA Corporate Plan 2018 to 2023 - GOV.UK \(www.gov.uk\)](http://www.gov.uk)

The Life Sciences Sector Deals - [Life sciences: Sector Deal - GOV.UK \(www.gov.uk\)](http://www.gov.uk)

The Independent Medicines & Medical Devices Safety (IMMDS) Review - [the Independent Medicines and Medical Devices safety Review \(immdsreview.org.uk\)](http://immdsreview.org.uk)

Cabinet Office Code of Conduct for Board members of Public Bodies - [Code of conduct for board members of public bodies - GOV.UK \(www.gov.uk\)](http://www.gov.uk)

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DHSC and MHRA Framework Agreement March 2016 - [DH and MHRA framework agreement - GOV.UK \(www.gov.uk\)](http://www.gov.uk)

# Section 2: How to Apply

## 2.1 Making an application

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

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

[appointments.team@dhsc.gov.uk](mailto:appointments.team@dhsc.gov.uk) – please quote **ref: VAC-1715** in the subject field.

Applications must be received by midday on 10 May 2021.

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 the MHRA or cause public confidence in the appointment to be jeopardised, it is important that you bring them to the attention of the Advisory 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. 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 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.

## Disability Confident Scheme

The Department of Health and Social Care values and promotes diversity and is committed to equality of opportunity for all and to the appointment of disabled people. As part of the Disability Confident Scheme, we guarantee an interview to anyone with a disability who applies under the Scheme and whose application meets the essential criteria for the post.

### What do we mean by a disability?

To be eligible for the Disability Confident Scheme you must have a disability or long-term health condition, which could be physical, sensory or mental and must be expected to last for at least 12 months. You do not have to be registered as a disabled person to apply under this scheme.

If you wish to apply under the DCS please complete section E of the Monitoring form and return it with your application.

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

For further information regarding the role of the MHRA and the role of a Non-Executive Director please arrange to speak to the Chair, Stephen Lightfoot, by contacting his assistant Jude Thompson on [chair@mhra.gov.uk](mailto:chair@mhra.gov.uk).

For further information regarding the selection process, please contact:

Ben Jones

Appointments Team

Tel: 0113 2546557

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Email: [Ben.Jones1@dhsc.gov.uk](mailto:Ben.Jones1@dhsc.gov.uk)

Please quote reference VAC-1715 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 10 May 2021
- Shortlisting complete:   by 24 May 2021
- Interviews held:               across 10 / 16 / 18 / 22 June 2021

The Advisory Assessment Panel will be:

- Liz Woodeson, DHSC Senior Sponsor for MHRA and Director of Medicines (panel chair)
- Stephen Lightfoot, Chair of MHRA
- Dr June Raine, CEO of MHRA
- Professor Sudhesh Kumar as Independent Panel Member

The Independent Panel Member is independent of both the Department of Health and Social Care and the 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 10 / 16 / 18 / 22 June 2021. The Appointments Team will email to let you know whether you have been invited to be interviewed. Interviews are likely to be conducted by video/ teleconference due to Covid-19 but if not, would be in central London.

- 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 DCS 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
- 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 delay 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 a NED 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 Disability Confident 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 Ben Jones on [Ben.Jones1@dhsc.gov.uk](mailto:Ben.Jones1@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 Steve Howell in the Department of Health and Social Care by emailing [Steve.Howell@dhsc.gov.uk](mailto:Steve.Howell@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 Ben Jones at [ben.jones1@dhsc.gov.uk](mailto:ben.jones1@dhsc.gov.uk)

## 2.4 How we will manage your personal information

Your personal information will be held in accordance with the General Data Protection Regulation. 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 Advisory Assessment 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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