Medicines & Healthcare products Regulatory Agency

Agency Board

Terms of Reference

Document Control[1]

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Document Change History

Date	Issuance/ Revision	Author	Description of Changes
09-2020	1.0	N/A	First draft
09-2020	1.1	N/A	Updates
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02-10-2020	1.3	N/A	First review by ExCo at 6 October meeting
21.09.2021	1.4	Stephen Lightfoot	Substantial update to Board ToR to reflect appointment of new members and new ways of working
18.12.2022	2	Carly McGurry	Transfer of Board ToR to Agency template
07.01.2023	2.1	Carly McGurry	Formatting improvements
01.03.2023	2.2	Carly McGurry	Change of delegated authority to reserved matters to more accurately reflect arrangements between Board and ExCo
27.03.2023	2.3	Carly McGurry	Updated following Board feedback to clarify distinct roles of Board and ExCo in relation to partnership agreements and future accommodation/location strategy
18.05.2023	2.4	Stephen Lightfoot	Added clarification that Executive Remuneration is delegated to ODRC
12/06/2023	2.5	Carly McGurry	Amendment to clarify quoracy requirements
29/06/2023	2.6	Carly McGurry	Clarification of public questions relating to the Board agenda only and publication of minutes of meetings held in public. Chair content that

			these minimal changes do not require further approval from the Board.
18/06/2024	3.0	Carly McGurry	Clarifying arrangements for delegation of authority by the CEO via ExCo, deleting reference to Delivery Plans and including a commitment to periodic independent review of Board effectiveness.
12/05/2025	4.0	Carly McGurry	Amending number of times the Board will meet under new chair and changing reference to sub-committees which have now taken new form.
24/06/2025	4.1	Carly McGurry	Further amendments following discussion at Board on 20 May, to clarify approach to public meetings and framework for sub-committees.
14/08/2025	4.2	‘Alani Vailahi	Amendment to PPEC as per Board action from the 8 July meeting. The Board approved the TOR following this amendment and in effect from 9 July 2025.
11/12/2025	5.0	Sarah Gilbert	Amendment to membership and frequency (sections 4.2, 5.3 and 9.1) following completion of refresh of the Board in September 2025. Approved at January 2026 Board meeting.

Distribution

To all ExCo members and advisors, to chairs of all management committees and added to Insite for use by all staff. Published on the Agency website.

[1] Document control to be annexed on ToR

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1. Introduction

1.1 These Terms of Reference set out the principles that should underpin the roles and responsibilities of members of the Agency Board, which should be consistent with the Government Code for Public Appointments[1], Code of Conduct for Board Members of Public Bodies[2], and Managing Public Money[3]. Details of the relationship between the Department of Health and Social Care (DHSC) and the Medicines and Healthcare products Regulatory Agency ('the Agency') are defined in the Framework Agreement[4].

2. Purpose of the Board

2.1. The role of the Board is to support the Chief Executive in their responsibility for the successful operation of the Agency. MHRA has a unitary Board with an equal number of Executive and Non-Executive Directors, plus a Non-Executive Chair (MHRA or Board Chair), supported by three Board Assurance Committees.

2.2. The Board is responsible for advising and agreeing the strategic direction of the Agency, endorsing the Agency's recommendations to ministers on key financial and performance targets as set out in corporate and delivery plans, and advising on and monitoring plans to ensure those targets are met. The Board operates independently in supporting the Chief Executive, as the Accounting Officer, in the effective delivery of services and overall performance of the Agency 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.

2.3. The Board has no involvement in any regulatory decisions affecting medicines, medical devices or any other products or services delivered by the Agency. These are the responsibility of the Chief Executive Officer, delegated as appropriate to Agency civil servants via the oversight and accountability of the Executive Committee.

2.4. Final decisions (and the responsibility and accountability for those) rest with the Chief Executive Officer as the Accounting Officer of the Agency.

3. Responsibility

3.1. The responsibilities and matters reserved for the Board are set out in full in the Schedule of Reserved Matters annexed to these Terms of Reference.

3.2. The Board provides strategic leadership to the organisation and, in support of that:

- Sets the overall strategic direction of the Agency, within the context of Ministerial direction;

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[1] https://www.gov.uk/government/publications/governance-code-for-public-appointments
[2] https://www.gov.uk/government/publications/code-of-conduct-for-board-members-of-public-bodies/code-of-conduct-for-board-members-of-public-bodies-june-2019
[3] https://www.gov.uk/government/publications/managing-public-money
[4] https://www.gov.uk/government/publications/dh-and-mhra-framework-agreement

- Approves the Agency's Corporate Plan, Business Plan and supporting strategies designed to enable achievement of the Agency's strategic objectives, and monitors performance against them;
- Holds the Executive to account for the performance and proper running of the organisation, including operating in accordance with legal and government requirements and those set out in the Agency's Framework Agreement with DHSC;
- Ensures that effective arrangements are in place to provide assurance, effective risk management, governance and internal control;
- Promotes effective dialogue between the Agency, its stakeholders, the DHSC and patients;
- Encourages and engenders robust and expansive patient engagement throughout the organisation;
- Agrees which decisions it will make and which will be taken by the Executive as per the Schedule of Reserved Matters;
- Ensures high standards of corporate governance and personal conduct;
- Monitors the performance of the Agency against core financial and operational objectives;
- Provides effective financial stewardship;
- Advises on executive remuneration through delegation to the People and Public Engagement Committee and
- Monitors and reviews its own effectiveness on at least an annual basis, with periodic independent review.

3.3. The Board does not exercise any line management or executive functions. It does not have any involvement in any regulatory decisions affecting medicines, medical devices, or blood components for transfusion or any other services delivered by the Agency. These are the responsibility of the Chief Executive Officer, supported by the Executive Committee and their staff.

3.4. The DHSC is responsible for assessing the performance of the MHRA Chair and the Chief Executive Officer. The MHRA Chair is responsible for assessing the performance of Non-Executive Directors and the Chief Executive Officer is responsible for assessing the performance of the Executive Directors.

4. Composition

4.1. The Board is led by a Non-Executive Chair, who is appointed by the Secretary of State for Health and Social Care. The Chair in turn is supported by a unitary Board comprising of not more than 16 individuals.

4.2. Board membership should be formed of up to eight Non-Executive Directors (NEDs), appointed through open competition by the Secretary of State for Health and Social Care, and an equal number of Executive Directors, excluding the Chair. The Chief Executive Officer will appoint the Executive members of the Board from the Executive Committee of the Agency. The current membership is 6 Non-Executive Directors and 6 Executives, plus the non-executive Chair.

4.3. The Chair will nominate a Non-Executive Director to be appointed as Deputy Chair of the Board with agreement from the remainder of the Board. The Deputy Chair should be able to deputise for the Chair so that Board business can continue if the Chair is not available for any reason.

4.4. The Chair will also nominate a Non-Executive Director to be appointed as Senior Independent Director of the Board with agreement from the remainder of the Board. The Senior Independent Director will be a sounding board for the Chair and will also be responsible for gathering feedback on the performance of the Chair on an annual basis, without the Chair present, to provide input into the Chair's annual appraisal with the senior DHSC sponsor. They would also be expected to meet with Board members and act as an intermediary if required.

5. Membership

5.1. The Non-Executive Directors of the Board do not represent any specific customer, sectoral or stakeholder interests. Ministers will take into account the balance of skills when NEDs are appointed so that the Agency Board has the requisite skills and experience profile to deliver the Corporate Plan and associated strategy. The primary function of the NEDs will be to provide constructive challenge, strategic guidance, offer specialist advice and hold the executive to account.

5.2. The NEDs will have Terms of Appointment clearly setting out what is required of them, how their performance will be appraised and the duration of their appointment. The Secretary of State for Health and Social Care may terminate an appointment for any reason before the expiry of the fixed period by giving three months' notice in writing. Additionally, a NED may resign by giving three months' notice in writing to the Secretary of State for Health and Social Care.

5.3. The following Agency's Executive Directors will be members of the Board and hold full voting rights on the Board. They will be appointed as Senior Civil Servants in their executive roles through the processes and conditions determined by the Civil Service Commission:

- Chief Executive Officer
- Chief Finance Officer
- Chief Medical and Scientific Officer
- Chief Technology and Digital Officer
- Chief Safety Officer
- Interim Executive Director, Healthcare Quality & Access

5.4. Committee meetings will also be regularly attended by other members of the Executive as the agenda demands. Other members of Agency staff shall be invited at the discretion of the Board when matters relating to their areas of responsibility are being discussed. The Board may ask any or all of those who normally attend but who are not members to withdraw to facilitate open and frank discussion of particular matters.

6. Conflicts

6.1. All members of the Board are subject to the Agency's Conflicts of Interest policy and the Cabinet Office's Code of Conduct for Board Members of Public Bodies. Members should pro-actively declare any potential conflicts of interest arising either from business on the agenda or from changes in their personal circumstances.

6.2. When a declaration of a potential conflict of interest is made, the Board Chair should determine an appropriate course of action, ranging from exclusion for a particular item of business to cessation of membership. Where the Board Chair has a conflict of interest, the other members led by the Senior Independent Director should determine the appropriate course of action.

7. Quorum

7.1. A quorum for meetings will consist of at least eight members, four of whom should be Non-Executive Directors and four of whom should be Executive Directors, plus the Non-Executive Chair or Deputy Chair.

7.2. If a member of the Board has been disqualified from participating in discussion on any matter by reason of a conflict of interest, they will no longer count towards the quorum.

7.3. If no quorum is available, then the Board cannot commit itself to any decision made.

8. Board Assurance Committees

8.1. The Board may set up committees and delegate authority to them, as the Board sees fit. The composition, terms of reference and reporting requirements of such committees shall be approved by the Board. The Board assurance committees currently constituted are:

- Audit and Risk Assurance Committee
- People and Public Engagement Committee
- Regulation and Safety Committee

8.2 The Chairs of each sub-committee will meet on a regular basis to discuss the activities of their committees, address any potential overlaps or multiple interests and to ensure quality advice to the full Board.

8.3 While the Board may make use of committees to assist its consideration of relevant matters, such committees are advisory in nature and responsibility for decisions remains with the Board. The Board retains responsibility for and endorses advice to the Chief Executive in all of these areas. The Board Chair should ensure that sufficient time is allowed at Board meetings for committees to report on the nature and content of discussion at sub-committee meetings, on recommendations made, and to agree on actions to be taken in response.

9. Frequency of Meetings

9.1. The Board will meet a minimum of six times per year but may meet more often if required. Of these meetings one meeting per year will be held in Scotland and one in either Wales or Northern Ireland, alternating annually. There will be two meetings held in public each year.

10. Format of Meetings

10.1. When Board Meetings are held in public, members of the public will have the opportunity to observe the Board conducting its business via an online broadcast. However, the Board Meetings will not be public meetings and members of the public will not be involved in making decisions at Board Meetings. The Board Chair will provide an opportunity for members of the public to ask questions directly of the Board on items on the agenda at each meeting if time allows.

10.2. Where a formal decision is required on a confidential item, a Board Meeting in Committee will be held.

10.3. The Board may also meet in a Board Seminar format where there is a more informal opportunity to meet external guests, provide input into the development of new strategies and take time for the Board's own development.

11. Attendance

11.1. The Chief People Officer, Director of Communications and Engagement, DHSC Senior Departmental Sponsor and representatives from the Devolved Administrations shall have a standing invitation to attend Board Meetings held in public and Board Meetings in Committee.

12. Secretariat

12.1. The Board is supported by a Company Secretary who should ensure that the Board has the policies, processes, information, time and resources that it needs in order to function effectively and efficiently.

12.2. The Board Secretariat will be responsible for the following, and is supported by timely and proactive input from all Board members:

- Preparing the agenda in consultation with the Board Chair;
- Developing and maintaining an effective eighteen-month schedule for the Board which enables timely co-ordination between assurance committees and the Board so that all standing business is captured and planned in advance;
- Commissioning Board papers and working with Agency staff to continually improve the quality of papers;
- Circulating Board papers to members and invitees a minimum of five working days before each meeting;
- Producing and circulating draft minutes of the Board meetings to members in advance of the next meeting; and

- Maintaining an action log.

13. Delegated Authority

13.1. The Board must operate within the limits of its authority as described in the Framework Agreement and in line with the associated Cabinet Office guidance on executive agencies. The Board may delegate some of its responsibilities to sub-committees to ensure sufficient scrutiny and engagement with the Executive. The Board's Schedule of Reserved Matters is available in Annex A.

14. Board Reporting

14.1. Recordings of Board Meetings Held in Public will be published on GOV.UK, together with the associated Board papers.

14.2. Minutes of the Board meetings will be provided to the Board, the Executive Committee and minutes of public meetings will be made available on the Agency's web page on GOV.UK.

15. Review of these Terms of Reference

15.1. These terms of reference will be agreed by the Board and reviewed at least annually at the beginning of each financial year.

ANNEX A: SCHEME OF DELEGATION

Certain matters are reserved for the Agency Board. The key aspects are summarised as follows:

Function / Duty / Responsibility of the Board	Responsibility of the Executive
Governance & Strategy	
Determining the overall strategic direction of the Agency. Consideration and approval of the Agency's Corporate Plan.	Preparation of the Agency's Corporate Plan for consideration and approval by the Board, ensuring early consultation with the Board.
Consideration and approval of the principle of formal strategic partnerships with other organisations.	Recommendations to the Board for formal strategic partnerships with other organisations and approval of detailed agreements.
Strategic principles governing operational policy relating to the exercise of the Agency's functions, powers and discretions.	Exercise of all the Agency's legal and administrative powers and discretions in furtherance of statutory functions, subject to escalating any high risk/high impact issues in line with the stated risk management approach.
Consideration of the annual Business Plan and associated budget(s).	Preparation of corporate plans and annual budgets in line with the Agency's strategic plan, ensuring early consultation with the Board.
Approval of changes to ToRs for standing committees of the Board and Board Sub-Committees.	To have regard to the annual review of ToRs for the Board and bring to the attention of the Board any changes for adoption / approval.
Approval of the Agency's risk appetite, risk management strategy and risk framework, and consideration of reports of the Audit and Risk Assurance Committee, in conjunction with the Accounting Officer.	The CEO as Accounting Officer will maintain the system of internal control and assurance framework within the Agency and provide the Board and Audit and Risk Assurance Committee with assurance on its ongoing effectiveness. Advise the Board and Audit and Risk Assurance Committee as to material changes thereto. Escalation of issues for consideration by the Board in accordance with the Agency's risk management strategy.
Assurance of appropriate overarching scheme of reservation and delegation within the Agency and its effective use	To advise the Board of arrangements for effective reservation and delegation, within the execution of the CEO's wider responsibilities (as delegated in this document) and evaluation of how those arrangements are working in practice

Approval of Annual Report and Accounts, in conjunction with and support of the Accounting Officer, and following a recommendation from ARAC.	Drawing up the annual report for adoption. Drawing up annual accounts including the annual governance statement for Audit and Risk Assurance Committee consideration and Board approval. The CEO will sign the Agency's Annual Report and Accounts as the Agency's Accounting Officer.
Delegate approval of the Agency's counter fraud and security management arrangements to the Audit & Risk Assurance Committee so that the Committee Chair can update the Board on significant issues in their regular Committee assurance report to the Board.	Preparation of such documents and policies to facilitate such approval with due regard to the Agency's stated risk appetite within this domain.
Delegate approval of the internal audit assurance programme to the Audit & Risk Assurance Committee so that the Committee Chair can update the Board on significant issues arising from the work of the appointed auditors in the regular Committee assurance report to the Board.	Reporting to the Audit and Risk Assurance Committee and the Board matters of significance arising from the work of internal and external auditors.
Consideration and approval of aspects of the corporate governance framework, including principles of good governance, corporate values statements, and such other aspects which may arise from time to time.	All matters of organisation below the level of CEO. Delegation of authority to other Agency staff and preparation and maintenance of a comprehensive scheme of delegation for the organisation.
Consideration and approval of appointments to Board assurance committees, following the recommendation of the Committee Chair.	
Financial / People / Operational	
Approval of the Agency's Standing Financial Instructions and financial scheme of delegation.	Preparation of the Standing Financial Instructions in consultation with the Resources Committee and Executive Committee.
Matters which may have a serious impact on the reputation of the Agency or have a political or public sensitivity.	Exercise of all the Agency's legal and administrative powers and discretions in furtherance of statutory functions, subject to escalating any high risk/high impact issues in line with the stated risk management approach.
Significant variations to the approved annual business plan and financial budget, where the variation would have a fundamental impact on the delivery of the	Mitigations and actions to correct variations to the approved annual business plan and financial budget so that assurance can be

Agency's strategy and its statutory responsibilities.	provided to the Board on the delivery of the agreed plans.
Confirmation of the regular performance reports and information required to provide appropriate scrutiny and assurance of the Agency's overall performance. The Board may ask the Executive Committee or one of the Board Assurance Committees to review any specific areas of concern in more detail so that recommendations for improvement can then be made back to the Board.	Informing the Board of progress in achieving performance objectives and advising of any significant variance from the approved operating plans and budget. Informing the Board of any significant issues in the operation of the Agency.
Approval of significant changes to the organisation, location, and People Strategy of the Agency.	Preparation of the People Strategy and associated policies in consultation with the People and Culture Committee and through the Executive Committee. Preparation of accommodation and location strategies and approval of contractual agreements.
The People and Patient Engagement Committee will make recommendations to the Chief Executive on the performance assessment and discretionary rewards for the Executive Directors.	All appointments and all other HR/people issues throughout the Agency.
Legal / Regulatory	
Approval of significant changes in the Agency's regulatory approach or strategy so that appropriate representations can be made to Ministers and the DHSC.	Exercise of all the Agency's legal and administrative powers and discretions in furtherance of statutory functions, subject to escalating any high risk/high impact issues in line with the stated risk management approach.