Medicines & Healthcare products Regulatory Agency

Board Operating Framework

Introduction

1. The Agency is an Executive Agency of the Department of Health and Social Care (the Department) and is a government trading fund. The main function of the Agency is to regulate medicines and medical devices, underpinned by science and research. The Agency also has an important role in bringing innovation safely to patients as rapidly as possible. The MHRA's specific functions include:

Statutory functions

- operating a system of licensing, classification, monitoring and enforcement to ensure that medicines for human use, sold or supplied in the UK, are of an acceptable standard;
- discharging statutory obligations, including those of the UK's EU competent authority, for medical devices and contributing to developing the safety and performance standards that support this work;
- ensuring compliance with statutory obligations relating to the investigation of medicines in clinical trials and assessing notifications or proposals for clinical trials from manufacturers of medical devices;
- operating and contributing to systems at both UK and EU level of post-marketing surveillance for medicines and medical devices, taking action to safeguard public health;
- ensuring compliance, in the UK, with statutory obligations relating to the manufacture, distribution, sale, labelling, advertising and promotion of medicines;
- designating and monitoring the performance of notified bodies that audit manufacturers of moderate and high-risk medical devices, and maintaining a register of all manufacturers placing medical devices on the UK market;
- devising and drawing up standards for the purity and potency of biological substances and designing appropriate test procedures;
- preparing, approving, holding and distributing standard preparations of biological substances;
- providing, or arranging for, the provision of laboratory testing facilities for the testing of biological substances, carrying out such tests, examining records of manufacture and quality control and reporting on the results;
- carrying out, or arranging for the carrying out, of research in connection with biological standards and control function;
- regulating the safety and quality of blood and blood components;

- managing the activities of the British Pharmacopoeia (BP) and work undertaken by BP staff relating to the European Pharmacopeia; discharging the functions of the UK Good Laboratory Practice Monitoring Authority (GLPMA);
- regulating consumer e cigarettes in line with the Tobacco Products Directive

Non-statutory functions

- managing the activities of the Clinical Practice Research Datalink (CPRD) using anonymised clinical records in support of a range of public health activities;
- representing the United Kingdom at, and collaborating with, European and other international bodies, on matters concerning: • the regulation of medicines and medical devices;
- development of medicines and devices regulation; and in relation to the establishment of standards, for the provision of standard preparations of, and the testing of biological substances.

2. Through the National Institute for Biological Standards and Control (NIBSC), the Agency is responsible for the standardisation and control of biological medicines, working both nationally and internationally.

3. The Agency, together with the NHS National Institute for Health Research (NIHR) jointly funds the Clinical Practice Research Datalink (CPRD) which is run as part of the Agency operations. CPRD is the English NHS observational data and interventional research service, designed to maximise the way anonymised NHS clinical data can be linked to enable many types of observational research and deliver research outputs that are beneficial to improving and safeguarding public health.

Responsibilities of the Board

4. The Board is primarily responsible for advising on the strategic development of the Agency and ensuring that targets set out in our business plan and endorsed by ministers are met.

5. 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, and at an EU 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.

- The Board's role is to provide oversight and raise concerns about the effectiveness of the risk management, governance and internal controls that have been implemented by the Agency (and/or Accounting Officer).

Composition of the Board

6. The Agency is supported 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 the Agency's Chair, Chief Executive and Chief Operating Officer, and up to nine non-executive members. Non-Executive members will be appointed by the Secretary of State following open competition and do not represent any specific customer, sectoral or stakeholder interests.
7. Non-Executive members of the Board should have terms of appointment clearly setting out what is required of them, how their performance will be appraised and the duration of their appointments.

Wider engagement with the Agency

8. The Board's Non-Executive Directors are encouraged to get involved with the work of the Agency through specific sponsor roles. For example, on Exiting the EU, business planning, business transformation, conflicts of interests, vaccines work, relations with the Devolved Administrations, whistleblowing, and the work of the Scientific Advisory Committee.

Declarations of interest

9. Members should pro-actively declare any potential conflicts of interest arising either from business on the agenda or from changes in their personal circumstances. The Chair should determine an appropriate course of action, from exclusion for a particular item of business to cessation of membership. Where the Chair has a conflict of interest, the other members present should determine the appropriate course of action. 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.

Chair

10. The Chair is responsible to the Secretary of State and will work closely with the Senior Departmental Sponsor to ensure that the Agency's affairs are conducted with probity and that the Agency's policies and actions support it in the discharge of its functions and duties efficiently and effectively and meet the Agency's objectives.

11. The Chair is responsible for:

- providing leadership to the Board and the Agency itself, for enabling all Board members to make a full contribution to the Board's affairs and for ensuring that the Board acts as a team for the benefit of the Agency and its stakeholders;
- annual evaluation and appraisal of the non-executive directors; and
- providing feedback on the CE's performance to the Permanent Secretary.

12. The Chair will meet the Secretary of State, or relevant Minister (or their nominee) at least once a year, including at an annual accountability meeting to discuss the Agency's strategy and performance. The Senior Departmental Sponsor will ensure that there is an annual objective setting and review process in place for the Chair.

Meetings of the Board

13. Meetings will be held up to nine times per financial year, together with two Board/ Corporate Executive Team strategic away days, which usually take place every six months. The Board does not meet in August.
14. Since 18 September 2015, when the Board adopted a unitary structure, the Chief Executive and the Chief Operating Officer now serve as executive members of the Board. Other executive directors may attend all Board meetings as observers.
15. A member of the Department of Health and Social Care's Legal Services attends to inform the Board on the Agency's business. Officials from the Department of Health and Social Care (England) and the three Devolved Administrations (Northern Ireland, Scotland, Wales), may attend as observers.
16. Since February 2016, the Agency has opened part of its programme of Board meetings to staff observers and members of the public. Up to fifteen staff observers and up to fifteen members of the public may attend the meetings of the Board in public session, which are usually held every quarter.

Chairing arrangements / calling a meeting

17. All meetings will be chaired by the Chair or, in his/her absence, the Deputy Chair. Where necessary, ad hoc meetings may also be called either by the Chair or Deputy Chair. In exceptional circumstances, should members of the Board be unable to join a Board meeting in person, they may join by telephone or video link.

Setting the agenda

18. The agenda for each meeting is prepared by the Board Secretary in consultation with the Chair and Chief Executive and is set out in the Forward Programme of Board Business, the plan for which is a standing item at each meeting. A draft agenda for the Board meeting is circulated a month in advance of the meeting in question.

Secretariat

19. The Board Secretariat will be responsible for:

- preparing the agenda in consultation with the Chair.

- commissioning Board papers.
- circulating Board papers to members and invitees, normally five working days before each meeting.
- producing and circulating draft minutes of the Board meetings to members, normally within ten working days after the meeting.
- maintaining an action log.

Board reporting

20. Directorate (Office of the Chair and Chief Executive) will provide the secretariat for the Board. Minutes of the Board meetings will be provided to the CET for information and consideration. The minutes of Board will be published on the Agency's page on GOV.UK.

Quorum

21. A quorum for meetings will consist of 6 members, one of whom must be an executive member of the Board. If a member of the Board has been disqualified from participating in discussion on any matter by reason of a conflict of interest, they shall no longer count towards the quorum. If no quorum is available, then the Board cannot commit itself to any decision made.

Board Committees

22. The Board may appoint Committees to provide assurance in relation to the operation and business of the Agency. The composition, terms of reference and reporting requirements of such committees shall be approved by the Board. The Board Committees are:

- Audit and Risk Assurance Committee
- Remuneration Committee

Code of Conduct

23. Board members must adhere to the Civil Service Code of Conduct. This includes a requirement for members to complete and maintain a register of declaration of interests as well as general standards of business conduct.

Reviewing the Operating Framework

24. This Operating Framework may be reviewed at any time with the agreement of the Board, but at least every two years.

Annexes:
Annex A: Board Terms of Reference
Annex B: Audit and Risk Assurance Committee Terms of Reference
Annex C: Remuneration Committee Terms of Reference
Annex D: MHRA Framework Document (March 2016)

ANNEX A

Board Terms of reference

These are the published terms of reference for the Medicines and Healthcare products Regulatory Agency.

The Board

Role

The Board is primarily responsible for advising on the strategic development of the Agency and ensuring that targets set out in our business plan and endorsed by ministers are met.

Membership

The Board will consist of not more than 12 individuals and will be chaired by the Agency chairman. Non-Executive members will be appointed by the Secretary of State following open competition and do not represent any specific customer, sectoral or stakeholder interests.

Since 18 September 2015, when the Board adopted a unitary structure, the Chief Executive and the Chief Operating Officer now serve as executive members of the Board. Other executive directors may attend all Board meetings as observers.

A member of the Department of Health and Social Care's Legal Services usually attends to inform the Board on the Agency's business.

Non-Executive members of the Board should have terms of appointment clearly setting out what is required of them, how their performance will be appraised and the duration of their appointments.

Members should pro-actively declare any potential conflicts of interest arising either from business on the agenda or from changes in their personal circumstances. The Chair should determine an appropriate course of action, from exclusion for a particular item of business to cessation of membership. Where the Chair has a conflict of interest, the other members present should determine the appropriate course of action. 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.

Responsibilities

The Board is primarily responsible for advising on the strategic development of the Agency, holding the executive to account and ensuring that targets set out in our business plan and endorsed by Ministers, are met.

The responsibilities of the Board are set out in the DH and MHRA framework agreement.

The Board is responsible for monitoring the implementation of ministers' objectives for the strategic direction of the Agency, taking into account the perspective(s) of its stakeholders, and advising Ministers and the Agency accordingly.

In particular this includes the content of the Agency's annual report including:

- corporate governance and financial management
- business strategy and corporate objectives
- five-year corporate plan (link needed) and annual business plan (link needed)
- key financial and performance targets
- culture and values
- internal and external communications management and quality

The Board monitors the effective, efficient and economic delivery of the Agency's objectives and ensures that the Agency fulfils its core objectives and complies with all statutory and administrative requirements for the use of Agency funds and the maintenance of the highest standards of corporate governance and public accountability.

The Board, as a whole, does not exercise any line management or executive functions, nor does it have a legal or constitutional role or any liability in respect of decisions of the executive. It does not determine the details of regulatory policy, nor does it have any involvement in any regulatory decisions affecting medicines or medical devices. These are the responsibility of the Chief Executive, working through Corporate Executive Team (CET) directors and their staff, and of the expert advisory committees.

The Board use their experience and expertise and meet these responsibilities by:

- meeting on a regular basis
- attending sub-committees, e.g. Audit and Risk Assurance Committee
- considering strategy papers from the CET and other Agency staff as necessary
- attending occasional Agency events including all-staff meetings, Agency annual lectures and informal briefing meeting with executive staff where necessary.

Meetings

Meetings will be held up to nine times per financial year, together with two Board/ Corporate Executive Team strategic away days, which usually take place every six months. The Board does not meet in August.

All meetings will be chaired by the Chair or, in his/her absence, the Deputy Chair.

Ad hoc meetings where necessary may also be called either by the Chair or Deputy Chair.

In exceptional circumstances, should members of the Board be are unable to join a Board meeting in person, they may join by telephone or video link.

Officials from the Department of Health and Social Care (England) and the three Devolved Administrations (Northern Ireland, Scotland, Wales), may attend as observers.

Since February 2016, the Agency has opened part of its programme of Board meetings to staff observers and members of the public. Up to fifteen staff observers and up to fifteen members of the public may attend the meetings of the Board in public session, which are usually held every quarter.

Quorum

A quorum for meetings will consist of 6 members, one of whom must be an executive member of the Board.

Secretariat

The Board Secretariat will be responsible for:

- preparing the agenda in consultation with the Chair.
- commissioning Board papers.
- circulating Board papers to members and invitees, normally five working days before each meeting.
- producing and circulating draft minutes of the Board meetings to members, normally within ten working days after the meeting.
- maintaining an action log.

Board reporting

Directorate (Office of the Chair and Chief Executive) will provide the secretariat for the Board. Minutes of the Board meetings will be provided to the CET for information and consideration. The minutes of Board will be made on the Agency's page on GOV.UK.

Corporate Executive Team

The Corporate Executive Team (CET) is the highest executive decision-making body of the agency.

The CET's primary responsibilities are to ensure that:

- the strategic direction of the agency is developed in co-ordination with the agency board
- the strategic direction, as set out in the 5-year corporate plan, is implemented and delivered through the business plan
- the agency's performance targets are met the agency follows the principles of good governance, including:
- risk management and assurance
- financial management and assurance
- information management and assurance
- health and safety assurance
- management of corporate ethics and conflicts of interest; and
- quality management and assurance
- oversight of the activities of the 3 centres within the agency

The CET will meet these responsibilities by:

- developing the 5-year corporate plan, setting out the strategic focus for the agency in the next period, for annual review and agreement by the AB
- agreeing, and overseeing the implementation of, the key strategies that cascade from the corporate plan, including on:
    - finance
    - workforce planning
    - communications
    - information technology
    - regulatory and standards

    - EU and international
    - Clinical Practice Research Datalink (CPRD)
    - innovation
- agreeing, and overseeing the implementation of, an annual business plan, aligned with the 5-year corporate plan
- monitoring of performance against the principles of good governance (as above)
- monitoring the performance and activities of the regulatory, National Institute for Biological Standards and Control (NIBSC) and CPRD centres by way of quarterly governance reports, which will include an assessment against key performance indicators – agreed by CET - for the NIBSC and CPRD centres
- providing a corporate view on specific issues that are brought to CET by directors
- agreeing all papers that are submitted by the executive to the AB
- monitoring of, and reporting to the agency board on, performance against the corporate plan, business plan and operations of the agency

The CET will devolve certain areas of its business to sub-groups, each chaired by a designated director. The CET may also initiate time-limited programmes of work, each led by a designated director. Each of these groups will have their own terms of reference, agreed by the CET.

Frequency of meetings

The CET will meet informally on a weekly basis to share intelligence on emerging issues and to highlight key events in the week ahead. These meetings do not formally consider strategy or governance matters.

The formal responsibilities of the CET will be carried out through a single monthly meeting.

The CET will also meet once per month for a CET mini away day to explore emerging strategic issues. Full away days will also be held.

CET reporting arrangements

Minutes of formal CET meetings will be provided to the agency board.

Quarterly governance reports from the following will be provided to the CET by:

- NIBSC senior management team, CPRD executive committee and the MHRA regulatory group (RG), covering the activities and performance of each of the 3 centres
- CET sub-groups and time-limited programmes of work

Minutes of the MHRA RG will be submitted to the CET for information together with the current issues register.

The directors of NIBSC and CPRD will make monthly reports to the CET on the activities of the senior management team and executive committee respectively.

Membership

The CET is chaired by the chief executive and has as members the directors of the corporate divisions, operating divisions and NIBSC and CPRD centres. A

representative from the Department of Health Legal Services shall also attend the CET.

The membership is:

- the Chief Executive as chair
- the directors of: devices division, communications division, information management division, policy division, finance and procurement, human resources, licensing division, inspection, standards and enforcement, vigilance and risk management of medicines, the NIBSC and CPRD

Alternates will be required where full members are unavailable.

Conflicts of interest

Members and alternates will comply with established procedures for .

Transparency

The agency's guiding principle is full transparency unless non-disclosure is justified on the basis of established freedom of information exemptions. Final agreed minutes of CET meetings will be published each month following any necessary redactions.

ANNEX B

MHRA Audit and Risk Assurance Committee

Terms of Reference

1. Role

1.1 The Board has established an Audit and Risk Assurance Committee as a Committee of the Board to support them and the Accounting Officer in their responsibilities for issues of risk, control and governance by reviewing the comprehensiveness of assurances in meeting the Board and Accounting Officer's assurance needs and reviewing the reliability and integrity of these assurances.

1.2 Minutes of the Audit and Risk Assurance Committee will be presented to the Board and to the Accounting Officer. Any advice from the committee will be highlighted.

2. Membership

2.1 The membership of the ARAC, appointed by the Board, will consist of four non-executive members of the Agency Board, one of whom will be appointed as Chair by the Chair of the Board. Any of the non-executive members can deputise in the Chair's absence. Members of the Corporate Executive Team will not be eligible for membership of the ARAC, but will attend Committee meetings by invitation from the Chair.

2.2 Members should together possess the appropriate range of skills in risk, governance and internal control, including recent and relevant financial experience, to enable engagement with financial management and reporting in the Agency.

2.3 The committee shall periodically, review its own performance, constitution and terms of reference and recommend any changes it considers necessary to the Board for approval. The ARAC Chair will ensure that a mechanism exists to appraise members' contributions to the committee. The Agency's Chair will carry out the annual appraisal of the ARAC Chair

2.4 Members should have terms of appointment clearly setting out what is required of them, how their performance will be appraised and the duration of the appointments. As NEDs, who make up the ARAC, are themselves appointed for duration of 3 years and subject to renewal, the same shall be applied to the duration of membership of the ARAC.

2.5 Members should pro-actively declare any potential conflicts of interest arising either from business on the agenda or from changes in their personal circumstances. The Chair should determine an appropriate course of action, from exclusion for a particular item of business to cessation of membership. Where the Chair has a conflict of interest, the other members present should determine the appropriate course of action.

2.6 The Committee may, with the Board's authority, co-opt persons outside the Agency to become members for a period not exceeding one year where there are insufficient appropriate non-executive board members available to join the Committee.

2.7 The Committee may with the Board's authority procure any additional specialist skills or knowledge that may be required at any particular time.

3. Meetings

3.1 Meetings will be held at least five times per financial year to coincide with the requirements of the Agency's business and accounting cycles.

3.2 All meetings will be chaired by the ARAC Chair or, in his/her absence, any of the other members present.

3.3 The secretariat will be provided by the Accounting Officer's staff.

3.4 Ad hoc meetings where necessary may also be called either by the Chair or the Accounting Officer.

3.5 A quorum for meetings will consist of two members.

3.6 The following persons should routinely attend all Committee meetings:

- The Accounting Officer
- The Chief Operating Officer
- The Deputy Director of Finance
- The Head of Internal Audit
- A representative from the External Auditor
- A representative from the Department of Health and Social Care.
- A senior official from NIBSC
- The Committee may also require any officers of the organisation to attend Committee meetings or to provide written reports to assist the Committee with its discussions on any particular matter.
- The Committee may, at the Chair's discretion, decide to meet without any non-members present for all or part of any meeting.

3.7 The ARAC Secretariat will be responsible for:

- preparing the agenda in consultation with the Chair.
- commissioning and quality-assuring Committee papers.
- circulating Committee papers to members and invitees, normally five working days before each meeting.
- producing and circulating draft minutes of the committee meetings to members and standing invitees, normally within ten working days after the meeting.
- maintaining an action log.
- maintaining the committee work plan.
- ensuring committee papers are maintained in accordance with the Code of Practice for Records Management.
- assist the Chair in preparing a short written report of the meeting to be presented to the board the following month.

4. Responsibilities

4.1 The ARAC will advise the Board and Accounting Officer on:

- the strategic processes for risk identification, assessment and mitigation;
- the adequacy of the Annual Governance Statement;
- the accounting policies, the accounts and the annual report of the organisation, including the process for review of the accounts prior to

submission for audit, levels of error identified, and management's letter of representation to the external auditors;

- the planned activity and results of both internal and external audit;
- the adequacy of management response to issues identified by audit activity, including external audit's management letter;
- the assurances relating to the risk management, Health & Safety, Conflict Of Interest policy and other corporate governance requirements for the organisation;
- proposals for tendering for either internal or external audit services or for purchase of non-audit services from the contractor that provides audit services, including review of their effectiveness;
- anti-fraud policies, whistle-blowing processes and arrangements for special investigations; and
- the results of the periodic reviews of the Committee's own effectiveness.
- the effectiveness of processes in place to deter and investigate fraud
- the effectiveness of processes which enable staff to raise concerns and processes for investigating concerns

5. Authority

5.1. The ARAC is authorised:

- to investigate any activity it deems necessary to carry out its duties;
- to seek any information it requires from any employee; and
- to employ the service of such advisers as it deems necessary or appropriate to fulfil its responsibilities. Such advisers may attend meetings by invitation of the Chairman of the ARAC.

5.2. Members of the Committee shall collectively and individually have direct access to the Chief Operating Officer and the Head of Internal Audit and the Agency's external auditors

6. Communication

6.1 The Minutes of the meetings, highlighting any action required (including that of the Accounting Officer) will be presented to the Agency Board and Accounting Officer and copied to the Internal Auditor, the External Auditor and the Corporate Executive Team.

6.2 The Chair of the ARAC will meet regularly with the Accounting Officer to discuss common issues around governance, Health & Safety, risk and control. An annual report, timed to support the governance statement and the finalisation of the financial accounts to meet the needs of both the Board and the Accounting Officer, will be prepared by the Committee summarising its work for the year and presenting the Committee's opinion on the comprehensiveness of assurances.

6.3 The Chair of the ARAC shall brief the Agency Board verbally on its activities at the next Board meeting after each committee meeting.

6.4 The members of the committee should meet privately with the Head of Internal Audit and the External Auditor at least annually, to ensure that there is clear understanding of expectations and mutual understanding of current issues.

ANNEX C

MHRA Remuneration Committee

Terms of Reference

Purpose:	To provide a formal and transparent process for determining executive remuneration.
Accountable to:	The MHRA Board. A confidential oral report of the meeting of the Remuneration Committee will be provided to the Board by the Chair of the Committee. Minutes of the Remuneration Committee meetings may contain personal data, for example about individual appraisal and are, therefore, not for publication on the Agency's website. It is likely that such minutes would be exempt under s40 of the Freedom of Information Act.
Chair:	A non-executive Director of the Agency
Membership and appointment:	Up to three non-executive Directors in addition to the Chair of the Committee. The Chair of the MHRA Board is not eligible for membership.
Quorum:	Three including the Chair
Sub-committees:	None
Terms of membership of the Committee:	The term of office is three years, with the option to serve a second three-year term.
Frequency of meetings:	The Remuneration Committee will meet in person or by tele-conference at least once a year.
Attendance:	Such members of staff and other persons as the Chair may require, normally: • The Chief Executive • The Director of Human Resources • The Chair of the MHRA Board
Delegated Authority:	To determine the remuneration and conditions of service (insofar as they differ from other staff) for the Chief Executive and Directors of the MHRA within the pay framework provided by the Civil Service
Review:	The Committee will review its own terms of reference, training needs and performance from time to time and at least triennially

Main Responsibilities:

1. Ensure that a sufficient mechanism exists to set objectives for and to review the work of the Chief Executive and Corporate Executive Team.

2. Receive a report from the Director of Human Resources setting out the relevant civil service pay guidance and current remuneration packages payable to each member of the Corporate Executive Team.

3. In consultation with the Chair and/or Chief Executive, make recommendations about the total individual remuneration package of the Chief Executive and each corporate director, including bonuses and incentive payments where applicable.

4. Review any proposals for severance arrangements for the Chief Executive or Corporate Directors

5. Ensure that executive pay is accurately and transparently reported in the Agency's accounts.

ANNEX D: MHRA Framework Document (March 2016)

https://www.gov.uk/government/publications/dh-and-mhra-framework-agreement

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