Medicines & Healthcare products Regulatory Agency

AGENDA FOR BOARD MEETING HELD IN PUBLIC

10:00 am – 12:00 pm on Tuesday 21 March 2023

Chair: Stephen Lightfoot

	AGENDA ITEM	**PURPOSE**	**PRESENTER**
10:00	INTRODUCTION		
	1. What is the purpose of this meeting and are there any absences?	Information	Chair
	2. Are there any new Declarations of Interest?	Information	All
	3. What were the minutes and actions from the last meeting?	Approval	Chair
	AGENCY PERFORMANCE		
10:15	4. What are the most important activities and priorities from the CEO's point of view?	Context	June Raine
10:35	5. What was the financial and people performance of the MHRA for the year up to 31 January 2023?	Assurance	Rose Braithwaite
10:55	6. What are the proposed financial budgets for 2023/24?	Approval	Rose Braithwaite
	EFFECTIVE GOVERNANCE		
11:15	7. What assurance can be provided by the Audit & Risk Assurance Committee?	Assurance	Michael Whitehouse
11:25	8. What assurance can be provided by the Annual Health & Safety Report of the MHRA?	Assurance	Marc Bailey
11:35	9. How effective are the Assurance Committees and how can the Terms of Reference for the Board, Executive Committee and Assurance Committees be improved?	Approval	Carly McGurry
	EXTERNAL PERSPECTIVE		
11:45	10. What questions do members of the public have about the items on this Board Meeting Agenda?	Public Engagement	Chair
12:00	CLOSE OF MEETING		

MHRA Board Declarations of Interest – March 2023

The MHRA 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, and advising on and monitoring plans to ensure those targets are met.

The Board supports the Chief Executive Officer 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.

The Board and its Non-Executive Directors have no involvement in any regulatory decisions affecting medicines, medical devices or any other products or services delivered by the Agency. These decisions are the responsibility of the Chief Executive Officer, supported by the Executive Committee.

Name and MHRA Role	Name of Other Company or Organisation	Nature of interest	Paid	Current
Stephen Lightfoot Chair of Board	NHS Sussex Integrated Care Board	Chair	Yes	Yes
	Sussex Community NHS Foundation Trust	Deputy Chair and Non-Executive Director	Yes	No
	Sussex Primary Care Limited	Chair and Director	No	No
	Gainsborough Property Development UK Limited	Director	No	No
Dame June Raine Chief Executive	World Health Organisation (WHO) Committee on Safety of Medicinal Products	Member	No	Yes
Dr Marc Bailey Chief Scientific Officer	Nokia Corporation	Ex-employee shareholder	No	Yes
Dr Junaid Bajwa Non-Executive Director	Microsoft	Employed (Chief Medical Scientist at Microsoft Research), Shareholder	Yes	Yes
	Merck Sharp and Dohme	Ex-employee shareholder	No	Yes
	Ondine biomedical	Non-Executive Director	Yes	Yes
	Novartis Industry Council	Advisory to UK Pharma Exec	Yes	Yes
	UCLH	Non-Executive Director	Yes	Yes
	Whittington NHS Trust	Associate Non-Executive Director	Yes	Yes
	NHS	GP, Physician (Sessional)	Yes	Yes
	Nuffield Health	Governor (NED)	Yes	Yes
	Nahdi Medical Corporation	Non-Executive Director	Yes	Yes
	DIA Global	Board Member	No	Yes

Name and MHRA Role	Name of Other Company or Organisation	Nature of interest	Paid	Current
Rose Braithwaite Chief Finance Officer	Mental Health Foundation	Treasurer	No	Yes
Amanda Calvert Non-Executive Director	Astrazeneca	Ex-employee shareholder Immediate family member	No	Yes
	Quince Consultancy Ltd	Provides consultancy services including companies in the healthcare sector.	Yes	Yes
	Athenex Pharma	Quince Consultancy providing strategic consultancy on oral oncology chemotherapy platform. ILAP applicant and Marketing Authorisation applicant.	Yes	Yes
	University of Manchester digital Experimental Cancer Medicine Team	Quince Consultancy providing strategy and data protection consultancy	Yes	No
	Cambridge Judge Business School	Member of Advisory Board	No	Yes
	The Guinness Partnership Limited – Housing Association	Non-executive Director, member of Audit Committee and Chair of Health and Safety Committee	Yes	Yes
	Fennix Pharmaceuticals	Founder of start-up company planning to develop oral chemotherapy product into Phase 2 trial. Not yet trading.	Yes	No
	High Value Manufacturing Catapult	Non-Executive Director	Yes	Yes
Dr Alison Cave Chief Safety Officer	None	N/A	N/A	N/A
Professor Graham Cooke Non-Executive Director & Deputy Chair	Imperial College NHS Trust and Chelsea & Westminster NHS Foundation Trust	Honorary NHS Consultant	Yes	Yes
	NIHR	NIHR Research Professor	Yes	Yes
	NIHR	Influenza platform trial in the UK	Yes	Yes
	NIHR	Chair DSMB (PROTECT-V trial)	No	Yes
	Pfizer	Pneumonia study with Imperial College Healthcare Partners	Yes	Yes
	30 Technology Ltd	Consultant/Advisor	Yes	Yes
	DNAnudge Ltd	Consultant/Advisor	No	Yes
	Seventh Sense Biosystems	Consultant/Advisor	Yes	Yes
	Debevoise and Plimpton LLP	Consultant/Advisor in relation to COVID protocols	Yes	No
	Sanofi CoV	Chair of End Point Review Committee for vaccine trial	Yes	Yes
	WHO	Chair of Committee for Selection and Use of Essential Medicines	No	Yes

Name and MHRA Role	Name of Other Company or Organisation	Nature of interest	Paid	Current
Dr Paul Goldsmith Non-Executive Director	Closed Loop Medicine Ltd	Shareholder, director & employee; ILAP applicant; user of CPRD; and MA submission	Yes	Yes
	Summit Inc	Shareholder	No	Yes
	Ieso Digital Health	Shareholder	No	Yes
	MDU Ltd	Director	Yes	Yes
	MDU Investments Ltd	Director	Yes	Yes
	NHS	Consultant Neurologist	Yes	Yes
	NHS	Clinical Senate Member	No	Yes
	Big Tent Foundation	Trustee	No	Yes
	Radix Group Limited	Trustee	No	Yes
	Sleepstation	Co-founder of original programme, 2012-2014	No	No
Claire Harrison Chief Digital & Technology Officer	None	N/A	N/A	N/A
Haider Husain Non-Executive Director	Healthinnova Limited	Chief Operating Officer	Yes	Yes
	Milton Keynes University Hospital NHS Foundation Trust	Non-Executive Director	Yes	Yes
	British Standards Institute	Panel Chair BS30440 – Use of AI within Healthcare	No	Yes
	Dementia Carers Count	Trustee	No	Yes
	World Wars Muslim Memorial Trust	Trustee	No	Yes
	Microsoft Corp	Ex-employee shareholder	Yes	No
	BBC	Family Member	No	Yes
	NHS Buckinghamshire, Oxfordshire and Berkshire West Integrated Care Board	Associate Non-Executive Director	Yes	Yes
Mercy Jeyasingham MBE Non-Executive Director	Royal College of Podiatry	Consultancy	Yes	No
	NHS South West London Integrated Care Board	Non-Executive Member	Yes	Yes
Raj Long Non-Executive Director	Gates Foundation	Employee – Deputy Director	Yes	Yes
	Bristol-Myers Squibb	Ex-Employee Shareholder	Yes	Yes
	RESOLVE (Sustainable solutions to critical social, health, and environmental challenges)	Scientific Advisory	No	Yes
	Novartis	Ex-Employee Shareholder	Yes	Yes
	EC IMI NEURONET EC Innovative Medicines Initiative (IMI) Non-Product	Scientist Advisory Board	No	Yes
	Gates Venture – EC Innovative Medicines Initiative (IMI) Non-Product – IMI European platform for Neurodegenerative Disorders	Advisory	Yes	Yes
	HUYA Bio	Access Advisory	Yes	No
	PAVIA – PV Africa Board (EC Funded)	Advisory Board	No	Yes

Name and MHRA Role	Name of Other Company or Organisation	Nature of interest	Paid	Current
	WHO – Sustainable COVAX Manufacturing Strategy for Regional Health Security	Advisory Expert	No	Yes
	UK Health Security Agency	Associate Non-Executive Board Member	Yes	Yes
Laura Squire OBE Chief Healthcare Quality & Access Officer	None	N/A	N/A	N/A
Michael Whitehouse OBE Non-Executive Director	South East Coast Ambulance Services NHS Foundation Trust	Deputy Chair & Senior Independent Non-Executive Director Chair of Audit Committee Chair of Charities Committee	Yes	Yes
	Cruse Bereavement Charity	Trustee Chair of Finance and Audit Committee	No	No
	Republic of Ireland Audit Office	Member of Audit Committee	No	Yes
	National Audit Office	Board Member and Chief Operating Officer until 17 April 2017	No	No
Glenn Wells Chief Partnerships Officer	None	N/A	N/A	N/A

Medicines and Healthcare products Regulatory Agency

Minutes of the Board Meeting Held in Public on 17th January 2023

(10:00 – 12:30)

Round Room, MHRA, 10 South Colonnade, E14 4PU

Present:

The Board

Stephen Lightfoot	Chair
Dr June Raine DBE	Chief Executive
Dr Marc Bailey	Chief Science, Research & Innovation Officer
Dr Junaid Bajwa	Non-Executive Director
Dr Alison Cave	Chief Safety Officer
Amanda Calvert	Non-Executive Director
Professor Graham Cooke	Non-Executive Director and Deputy Chair
Dr Paul Goldsmith	Non-Executive Director
Claire Harrison	Chief Digital & Technology Officer
Haider Husain	Non-Executive Director
Mercy Jeyasingham MBE	Non-Executive Director
Raj Long	Non-Executive Director
Dr Laura Squire OBE	Chief Healthcare Quality & Access Officer
John Taylor	Interim Chief Finance Officer
Dr Glenn Wells	Chief Partnerships Officer

Others in attendance

Vanessa Birchall-Scott	Director of Human Resources, MHRA
Rachel Bosworth	Director of Communications and Engagement, MHRA
Kathryn Glover	Deputy Director, Medicines Regulation and Prescribing, DHSC
Carly McGurry	Director of Governance, MHRA
Natalie Richards	Head of the Executive Office, MHRA

INTRODUCTION

Item 1: What is the purpose of this meeting and who are the Board Directors?

1.1 The Chair set out his expectations and priorities for this Board meeting held in public which was being live streamed to the registered audience and recorded. The Chair welcomed everyone to the meeting, including a broad range of observers including patients and members of the public, representatives of patient groups, healthcare professionals, government officials, industry, media and MHRA staff.

Item 2: Are there any Apologies or Declarations of Interest?

2.1 Apologies were received from Michael Whitehouse, Non-Executive Director; Alison Strath, Chief Pharmaceutical Officer for Scotland; Greig Chalmers, Head of Chief Medical Officer's Policy Division in the Scottish Government; and Cathy Harrison, Chief Pharmaceutical Officer for Northern Ireland.

2.2 The Board reviewed the Declarations of Interest (DOIs) for all MHRA Board members. No new declarations were made this month. The Chair reviewed the existing DOIs and was satisfied that there were no conflicts of interest preventing any Board Member from participating in the full agenda of this meeting.

Item 3: What were the minutes and actions from the last meeting?

3.1 The Board reviewed the minutes and actions from the last meeting and updates were provided.

AGENCY PERFORMANCE

Item 4: What are the most important activities and priorities from the CEO's point of view?

4.1 Dr June Raine presented the Chief Executive's monthly report, which covered the following:

(i) Scientific Research and Innovation – including latest updates on vaccine and blood products control testing; rotavirus vaccine guidance; cell therapies; Mpox (formerly Monkeypox) research; Marburg virus disease; influenza candidate vaccine viruses; the Innovative Licensing and Access Pathway (ILAP);

(ii) Healthcare Access – including updates on COVID-19 vaccines and therapeutics; medicines for Group A Streptococcal infection; prostate cancer medicines; cannabis-based medicines; the Regulators' Pioneer Fund; and product information;

(iii) Patient Safety – including updates on COVID-19 Vaccine reports; sodium valproate risk minimisation; the lenalidomide Pregnancy Prevention Programme; the Infected Blood Inquiry; a naloxone product defect; promoting adverse event reporting; and the Criminal Enforcement Unit;

(iv) Patient and Public Engagement – including updates on the Patient Involvement Strategy; and the Customer Experience Centre;

(vi) Partnerships – National and International– including updates on the Medical Devices regulatory framework; the ACCESS Consortium; international guidance and harmonisation; scientific communication and collaboration; and Intelligent Automation;

(vii) Dynamic Organisation – including updates on transforming MHRA services; the Regulatory Management System; a quality audit for diagnostics; the annual Civil Service People Survey; and the MHRA People Strategy; and

(viii) Financial Sustainability – including an update on the fees consultation.

4.2 The Board thanked Dr Raine for her report and thanked all MHRA staff for the excellent work over the last month. The Board provided comments relating to improvements to the Patient Information Leaflet; minimising risks associated with sodium valproate and implementation of safety measures, noting that an action was taken for the Patient Safety and Engagement Committee (PSEC) to review this at an upcoming meeting; the Infected Blood Inquiry; sharing experiences with other regulators; maximising the Agency's chances to benefit from sources of external funding in work such as the field of AI; focusing on emerging technologies; improving and transforming the Agency's services; and utilising the Customer Experience Centre as a source of information and feedback.

Action 89: PSEC to review the implementation of sodium valproate safety measures at a future meeting ***Mercy Jeyasingham***

4.3 The Board provided further comments relating to the wide range of communications tools the Agency utilises to issue safety updates such as Drug Safety Update; maximising partnerships with other Arm's-Length Bodies to develop innovation and science strategy, and establish the Agency's place within the research ecosystem; and the Access Consortium and the Agency's focus for the chairship. The Board noted Dr Raine's report with thanks.

Item 5: What was the financial and people performance of the MHRA for the year up to 30 November 2022?

5.1 The Board considered a report on operational performance of the Agency and provided comments relating to the underspend on capital expenditure, and ensuring multi-year projects are adequately funded and tracked, now that MHRA capital spending will form part of the overall DHSC capital spend and the impact on financial planning; filing vacancies as a priority, noting that there have been a number of successful recruitments; supporting staff through the cost of living crisis; addressing the level of unpaid debt to the Agency – an action was taken to explore the feasibility of deprioritising MA applications for companies who have unpaid debts with the Agency, without compromising public health, to help address the established medicines backlog. The Board noted the report with thanks.

Action 90 17/01/23: Explore the feasibility of deprioritising MA applications for companies who have unpaid debts with the Agency, without compromising public health, to help address the established medicines backlog.
Laura Squire & Rose Braithwaite

Item 6: What assurance can be provided by the Audit & Risk Assurance Committee?

6.1 The Board considered an assurance report provided by the Audit & Risk Assurance Committee (ARAC). The ARAC met informally on 13 December and considered an update on progress in addressing the issues raised by the Health and Safety Executive at the South Mimms site; reviewed progress in responding to external audit's recommendations; and considered the Agency's current financial performance. The recently appointed Risk Manager set out the plan and timetable for enhancing the Agency's approach to risk management; and the ARAC considered four Internal Audit reports on: the Innovative Licensing Access Pathway (ILAP); Financial Controls; Payroll; and Compliance with Cabinet Office Spending Controls. The National Audit Office (NAO) and KPMG plan for their audit of the MHRA's 2022-23 Financial Statements was reviewed; the Agency's timetable for producing its annual report to meet the Parliament's statutory timetable was reviewed; and the Agency's most recent complaints report was considered.

6.2 The Board considered the assurance report and provided comments related to risk management horizon scanning; joint use of committees; the importance of robust health and safety systems to the Agency's operations; and the Agency's Specified Animal Pathogens Order licence. The Board noted the report for assurance.

DYNAMIC ORGANISATION

Item 7: How will the new MHRA People Strategy improve the recruitment, diversity, development and retention of our staff to deliver our statutory responsibilities?

7.1 The Board considered a paper describing how the new MHRA People Strategy will improve the recruitment, diversity, development and retention of our staff to deliver the MHRA's statutory responsibilities. Following extensive consultation, approval by the Executive Committee (ExCo) and launch of the "Putting our People First" people strategy on 6 December 2022, a reflection was taken upon the role of this strategy in driving forward progress, with specific reference to recruitment, diversity, development and retention of the people delivering agency responsibilities. This is affirmation of ExCo's commitment to put our people at the centre of how we do what we do, including making the MHRA a great place to work and investing in our talent and expertise at every level.

7.2 The Board noted the report and provided comments relating to the review of this strategy which was undertaken by the Organisational Development and Remuneration Committee (ODRC), where the importance of communication using examples and stories to bring this strategy to life with staff in the Agency; enabling staff to understand the Agency's reputation externally and how this reflects upon them; utilising various initiatives including events, blogs, INsite updates, team meetings and other activities to promote the strategy at a more local level; and reviewing other comparable organisation's strategies to share ideas and ensure the strategy is appropriate for our Agency.

7.3 The Board provided further comments relating to how it is important that staff leaving the Agency to move on to new challenges is viewed in a good light as this demonstrates the Agency as a vital role in people's careers; the importance of being open about what is possible and what is not possible in relation to pay conditions; using the shadow ExCo and One Agency Leadership Group (OALG) to embed the strategy; the importance of building an inclusive and diverse culture; focusing on attracting the best people to the Agency, enabling personal development and driving up performance and delivery. The Board was very supportive and endorsed the strategy, and gave thanks to all involved in developing the strategy, although recommended that the strategy should be given a new title as it already had a strategy of 'putting patients first'.

Action 91: Implement the People Strategy and propose a new title as we cannot put patients first and put our people first. ***Vanessa Birchall-Scott***

Item 8: What assurance can be provided by the Organisational Development & Remuneration Committee?

8.1 The Board considered an assurance report provided by the ODRC. The ODRC met on 5 January 2023 and reviewed and discussed the actions and plans to improve employee satisfaction and motivation following the establishment of the new organisational structure; reviewed and discussed the progress in delivering the services that underpin the One Agency operating model and delivery of the business plan; reviewed the progress for delivery of the Regulatory Management System (RMS) programme; and review ODRC effectiveness.

8.2 The Board reviewed the ODRC assurance report and provided comments relating to the review of Terms of Reference for each of the Board Assurance Committees which will come to the March 2023 Board meeting; the importance of maintaining pace with the Regulatory Management System programme; the Transformation Gateway review, and an action was taken to share the results of this review with the Board; and the importance of effective communication. The Board noted the report for assurance.

Action 92: Share the results of the gateway review of the transformation programme with the Board. ***Mick Foy***

PATIENT SAFETY

Item 9: What assurance can be provided by the Patient Safety & Engagement Committee?

9.1 The Board considered an assurance report provided by the Patient Safety and Engagement Committee (PSEC). The PSEC discussed two main areas at its meeting on 16 December 2022 – the publishing of safety "signals" and the use of risk benefit workshops to inform communications with the public and health professionals. PSEC had also conducted business via email to sign off the one-year update on the Patient Involvement Strategy to ensure its timely publication in November 2022.

9.2 The Board noted the update and provided comments relating to assurance on accountability and transparency through publishing safety signals; the importance in effective communication of the fact that that not all safety reports will result in regulatory action, however the extent of analysis and consideration given to each signal will provide assurance to stakeholders; assurance on diversity in particular stakeholders with low literacy; increasing reach across different healthcare professional groups; increasing outreach to GPs; tackling misinformation; development of a risk communications strategy; working with other stakeholders such as the Care Quality Commission; and ensuring advice the MHRA provides is aligned with other key health partners. The Board noted the PSEC assurance report with thanks.

GOVERNANCE

Item 10: How will the Assurance and Governance Framework of the MHRA continue to be improved?

10.1 The Board considered a report describing how the Assurance and Governance Framework of the MHRA will continue to be improved, through reviewing the most critical risks to the achievement of the Agency's strategic objectives for discussion and review. The Board considered how to ensure the identified risks are mitigated throughout the Agency beyond the prescribed Government risk management process. The Board agreed that the Agency's most critical risks were represented throughout this paper; and agreed the correct programme of work is in place to develop the Agency's risk management capabilities. It was noted that the MHRA Framework Agreement with DHSC has been finalised and is awaiting Treasury sign-off. The Board noted that it is vital to establish delegated authority as described in the Framework Agreement for clarity to deliver the Agency's objectives. The Board endorsed the Assurance and Governance Framework with thanks.

EXTERNAL PERSPECTIVE

Item 11: What questions do members of the public have for the MHRA Board?

11.1 The Board answered a range of questions which had been submitted by members of the public before and during the meeting

ANY OTHER BUSINESS

12.1 The Chair noted with sadness the death of Professor Sir Michael Rawlins, who was the Chair of the MHRA for six years, from 2014 until 2020. The Chair noted Sir Michael's outstanding achievements in the field of pharmacology and offered the MHRA's sincere condolences to his family on behalf of the Board.

12.2 The Chair recorded his and the Board's formal thanks to John Taylor for his term as Interim Chief Finance Officer at the Agency and welcomed Rose Braithwaite who will be appointed as the permanent Chief Finance Officer from 1 February 2023.

12.3 No other items of business were recorded and the Chair closed the meeting.

ACTIONS FROM MHRA BOARD MEETING IN PUBLIC – 17th January 2023

The actions highlighted in red are due this month

Action Number	Action	Owner	Date	Status
Carried Forward from previous meetings				
29	16/03/21: Present an Agency Science Strategy to the Board. 15/11/22: Revise the Science Strategy to include clear prioritisation; and greater inclusion of in-house expertise on behavioural science with a complementary expert group. Include vaccines work as a specific area of expertise, alongside biologics and the UK Stem Cell Bank, to create a distinctive offering to make the UK an internationally recognised centre of excellence in this field. A review of scientific committees should also be undertaken. Present a further update to the Board in March 2023.	Marc Bailey	~~21/09/21~~ ~~16/11/21~~ ~~17/05/22~~ ~~15/11/22~~ 21/03/23	Verbal Update
43	15/06/21: A revised assurance and governance framework for the new MHRA organisation should be presented to Board.	Carly McGurry	~~15/02/22~~ ~~17/05/22~~ ~~20/09/22~~ 21/03/23	Completed
51	15/11/22: Include performance reports on Digital and Partnerships in future quarterly reports. There should be greater inclusion of trends in the report accompanied by more in-depth interpretation in the narrative.	Rose Braithwaite	21/02/23	Completed
59	21/09/21: Board assurance committees to review their combined effectiveness and hold a board discussion on this topic.	Michael Whitehouse, Mercy Jeyasingham, & Mandy Calvert	~~15/03/22~~ ~~16/08/22~~ ~~13/12/22~~ ~~17/01/23~~ 21/03/23	On Agenda
62	19/10/21: Review the Corporate Risk Register to consider whether all strategic risks to Agency outcomes are accurately captured.	Carly McGurry	~~19/04/22~~ ~~17/11/22~~ ~~17/01/23~~ 18/04/23	

70	18/01/22: Develop and present a Data Strategy to the Board	Alison Cave & Claire Harrison	~~17/05/22~~ ~~18/10/22~~ ~~15/11/22~~ 18/04/23	
71	18/01/22: Using the input from the public consultation and Board discussion, develop and publish a new regulatory framework for Artificial Intelligence as a Medical Device	Laura Squire	~~21/06/22~~ ~~20/09/22~~ ~~21/03/23~~ 16/05/23	
73	15/02/22: Develop a Sustainability Strategy	Glenn Wells	~~17/01/23~~ 16/01/24	
79	19/04/22: Hold a discussion on the Yellow Card Biobank at an upcoming Board meeting	Alison Cave	~~21/03/23~~ 16/05/23	
80	19/04/22: Implement the Budget as approved by the Board for 2022/23. Ensure the deficit is balanced by end of the year.	ExCo	31/03/23	Verbal Update
86	20/09/22: Work Programme for the ODRC to be developed and shared; identify time for ODRC Chair to speak with Chief Officers about their services 15/11/22: This is in progress.	Mandy Calvert	~~15/11/22~~ ~~17/01/23~~ 21/03/23	Completed
88	Present the Agency's Compliance Strategy to the Board	Laura Squire	~~21/02/23~~ 16/05/23	
New Actions				
89	17/01/23: PSEC to review the implementation of sodium valproate safety measures at a future agenda	Mercy Jeyasingham	~~21/03/23~~ 18/04/23	
90	17/01/23: Explore the feasibility of deprioritising MA applications for companies who have unpaid debts with the Agency, without compromising public health, to help address the established medicines backlog.	Laura Squire & Rose Braithwaite	21/03/23	Verbal Update
91	17/01/23: Implement the People Strategy and propose a new title as we cannot put patients first and put our people first.	Vanessa Birchall-Scott	21/03/23	Completed

92	Share the results of the gateway review of the transformation programme with the Board	Mick Foy	21/02/23	Completed

Medicines & Healthcare products Regulatory Agency

BOARD MEETING HELD IN PUBLIC

21 March 2023

Title	**What are the most important activities and priorities from the CEO's point of view?**
Board Sponsor	June Raine
Purpose of Paper	Context

What are the most important activities and priorities from the CEO's point of view?

'TOP 10' HEADLINES

- A cross-Agency team has been created to work at pace to deliver an end-to-end regulatory pathway for personalised immunotherapy particularly cancer vaccines
- The vaccine used in response to the 2022 global mpox outbreak (Modified Vaccinia Ankara) has been evaluated by our safety and surveillance team as acceptably safe
- We have progressed our leading stem cell research by extending a collaboration with the Japanese developer of an automated 'robot' system to grow human embryonic stem cells
- Pholcodine containing cough and cold medicines were recalled as a precaution due to a known risk of a serious interaction with muscle relaxants during surgery
- We participated in a Life Sciences Council advisory group on future medical devices regulation, prioritising safe innovation, international recognition and system capacity
- We held a workshop on In Vitro Diagnostics with Office of Life Sciences, National Institute for Health and Care Research and the National Institute for Heath and Care Excellence
- The Clinical Practice Research Datalink is supporting recruitment to the Long Covid Study via a decentralised approach, allowing participation by a wider, representative population
- The Criminal Enforcement Unit's partnership with Border Force led to the seizure of almost 200,000 doses of illegally traded medicines, valued at more than £0.5 million
- The updated legislation on Fees for Medical Devices and Blood Safety and Quality was laid in Parliament and will come into force in April, a vital step for our financial sustainability
- To attract new talent to the Agency, we are launching an in-house graduate scheme to attract up to 8 high-potential science graduates for a 3-year programme from September

SCIENTIFIC RESEARCH AND INNOVATION

Influenza

1.1 Following the WHO vaccine composition meeting held in Geneva in February, the WHO announced the recommendations for the viral composition of influenza vaccines for the 2023-2024 influenza season in the northern hemisphere. The WHO Essential Regulatory Laboratory (R&D) contributed to the meeting by providing scientific advice and data from laboratory analysis of human post vaccination serum samples. Following the WHO decision, we are working with the WHO ERL network to generate and provide potency reagents to manufacturers, ensuring relevant and effective vaccines for the next influenza season.

New SARS-CoV-2 variants

1.2 "Agility" is a Coalition for Epidemic Preparedness Innovations (CEPI)-funded project to assess new SARS-CoV-2 variants. In collaboration with UK Health Security Agency, R&D Vaccines scientists have evaluated the neutralisation profile of a variety of isolates against panels of samples from convalescent patients or vaccinees and reference materials, using live neutralisation assays. Data generated through this Agility project have been published in the *Viruses*, 'Assessment of the Biological Impact of SARS-CoV-2 Genetic Variation Using an Authentic Virus Neutralisation Assay with Convalescent Plasma, Vaccinee Sera, and Standard Reagents'.

Polio

1.3 Scientists in the Research & Development Vaccines team have contributed to a high impact scientific publication in 'Frontiers in Immunology' describing the clearance of longstanding, immune-deficiency-associated, vaccine-derived polio virus infection (> 30 years) following remdesivir therapy for chronic SARS-CoV-2 infection. Polio viruses from such patients are highly virulent with the potential to cause disease and outbreaks in unimmunised or poorly immunised communities. The data provide strong justification for further clinical studies of remdesivir treatment as a potentially curative intervention in immunodeficient patients with long-term poliovirus infection. R&D Vaccines scientists published a paper in Vaccines, "Effect of maternal immunisation with multivalent vaccines containing inactivated poliovirus vaccine (IPV) on infant IPV immune response: A phase 4, multi-centre randomised trial", in collaboration with scientists from UKHSA and Imperial College London.

Group B streptococcus

1.4 As part of our role in supporting vaccine development for low- and middle-income countries, Research & Development (R&D) Vaccine scientists have signed a contract with PATH, a global team of innovators working to eliminate health inequities, to prepare group B streptococcus (GBS) capsular polysaccharides (CPS) conjugated to poly-L-lysine. These reference reagents will be used in the development and validation of a multiplex immunoassay (MIA-Luminex) for assessing the immunogenicity of a six valent GBS vaccine for pregnant women to protect infants and new-borns from this potentially fatal disease.

UK Stem Cell Bank

1.5 Scientists in the R&D Biotherapeutics and Advanced Therapies Team have extended a collaboration with Sinfonia Technology Company in Japan. The project will assess the ability of an automated 'robotic' cell expansion system to grow human embryonic stem cells, comparing the quality of these cells with those grown by a highly skilled stem cell biologist. The team also attended the inaugural COST EU-funded HaploIPS meeting, an ambitious project seeking to generate a large bank of carefully selected induced pluripotent stem cell lines that will be immune compatible with most of the world's population. Our scientists will initially contribute their expertise to reviews of the current field and drafting of guidelines.

Anti-tumour immunity

1.6 Scientists in the R&D Biotherapeutics and Advanced Therapies Team have collaborated with King's College London to explore generation of Trastuzumab conjugates for induction of anti-tumour immunity. They showed that stochastic conjugates are impaired in their target binding properties whereas site-specific conjugates are fully functional and induced effective anti-tumour immunity in a transgenic mouse model. This demonstrates that antibody-adjuvant conjugates targeting tumour tissue are an effective tool to explore the

synergistic effects of two immunotherapeutic agents for the induction of antigen-specific anti-tumour immunity. The manuscript describing this study was accepted by PLOS ONE and will be published soon.

Antibody standards

1.7 Scientists in R&D and Standards Lifecycle contributed as experts to the WHO working group on the assignment of units to WHO International Standards for antibody. The outcome of the meeting will be presented as a recommendation at the Spring meeting of the WHO Expert Committee on Biological Standardization

WHO Guidelines on evaluation of biosimilars

1.8 As part of our work on biosimilar medicines and our continued collaboration with WHO, a representative from the R&D Biotherapeutics and Advanced Therapies team served as a drafting group member and rapporteur at the consultation meeting for revision of the 'WHO Guidelines on evaluation of biosimilars', established in April 2022. The revised guideline which replaced previous biosimilar guidelines issued in 2009, has a greater emphasis on quality and functional in vitro assessment and enables the reduction of cost and timelines for development and supports streamlined regulatory approval for availability of biosimilars, an approach also advocated by the MHRA in its biosimilar guidance. This contribution resulted in a meeting report published in 2022, and more recently in a scientific publication 'WHO guidelines on biosimilars: Toward improved access to safe and effective products.'

Formulation science

1.9 Scientists in the R&D Analytical and Biological Sciences team were successful in obtaining two years of Innovate UK funding under the Digitalisation and Automation of Medicines R&D and Manufacture call, as part of a Consortium to further investigate the use of novel process analytical technology in freeze drying. The Consortium brings us together with two universities and four industry partners.

Innovation Accelerator

1.10 The Innovation Accelerator (IA) team continues to evolve its approach to horizon scanning and is increasingly focusing its attention on Actionable Horizon Scanning Signals (AHSS). An AHSS can be defined as a signal that results in identifying a need to change what we do, how we do it, who is involved or expanding what we know. As part of this approach, the IA published a case study to raise the awareness of the concept and seek new signals.

Clinical Trials

1.11 Members of the Clinical Trials and the Strategic Programme Delivery (SPD) team are working together to find solutions to resolve the current backlog of clinical trials work. A model of time and resource to process applications the has been created to estimate when the backlog will be cleared given the current plans and constraints and is being updated on a weekly basis. SPD are working with Clinical Trials staff to explore further process and operational improvements to transform the current assessment model.

Cancer vaccines

1.12 Cancer vaccines have the potential to transform patient outcomes. The personalised nature – using genomic sequencing of the patient's tumour to create a vaccine that invokes an immune response – has shown promising signs in initial clinical trials. With the potential for on-site manufacturing to ensure vaccines can be developed and administered as quickly

as possible, should the early promise be realised then a new, novel approach to regulation may be required. We are working at pace to consider the end-to-end regulatory pathway that will be needed to ensure that personalised cancer vaccines are both safe and effective, with the potential to adapt the pathway for other personalised medicines

HEALTHCARE ACCESS

Innovative medicines

2.1 We authorised the Moderna (Spikevax) bivalent BA.4/5 COVID-19 vaccine for use in individuals aged 12 years and older, after seeking the advice of the CHM and the COVID-19 vaccine benefit-risk expert working group. We also authorised the new active substance maralixibat (Livmarli), an oral solution for the treatment of cholestatic pruritis in patients aged 2 years and older with Alagille syndrome. This is a rare genetic disorder which affects multiple organs, one aspect being a reduction in the number of bile ducts.

Established medicines

2.2 Public health continues to be our priority and this month, 15 expedited marketing authorisation variations were processed to ensure medicines supply was maintained. A programme of work is under way to address work queues for some application types, informed by a Task & Finish group with industry representatives. Applications for marketing authorisations for generic medicines are being processed at the rate they are being received. Recruitment also continues to be a focus with two further pharmaceutical assessors starting within the group and beginning their 2-year training programme to become accredited assessors. A project plan has been developed to remove backlogs and deliver a sustainable process that is able to deliver applications on time and right first time.

Manufacturing and Distribution

2.3 We held a 2-day symposium on Manufacturing and Distribution practice with 350 in person delegates and a further 900 delegates attending via a livestream. This was a welcome return to what was previously an annual event, extended for the first time by the livestream option. This hybrid approach allowed us to expand our reach and provided flexibility for stakeholders across the blood, manufacturing, and distribution sectors. The MHRA teams presented on a variety of topics including regulatory changes and changes to regulatory guidance and offered the opportunity for delegates to hear directly from the teams on several key topics. This event was an important opportunity to inform our stakeholders, and to drive compliance.

Medical Devices regulation

2.4 The Advisory Group established in December by the Life Sciences Council, comprising the MHRA, the Association of British Health Tech Industries, the Office of Life Sciences and the Department of Health and Social Care, reached a consensus on a number of proposals that will shape the future UK regulation of medical devices. Key recommendations encompassed three main priority areas: routes to bring innovative medtech products safely and swiftly to patients; UK recognition of approvals by stringent regulators internationally; and building system capacity. Plans are in place to publish the findings as soon as possible, with the aim of assuring the industry of the ambitions for the new UK regime and minimising the risk of loss of certain medical devices from UK market.

Regulation of innovative In-Vitro Diagnostics

2.5 We held a workshop with the British in-vitro Diagnostics Association (BIVDA) aimed at articulating the UK's in-vitro diagnostics (IVD) ecosystem, considering the gaps, and identifying where the MHRA can add most value. The workshop captured the barriers and enablers to the development of innovative IVDs, and the pre-market support required from MHRA. Presentations were given by the Office of Life Sciences, DHSC, Innovate UK, the Accelerated Access Collaborative, the National Institute for Health and Care Research, an Academic Health Science Network and NICE to set the scene. A request for earlier engagement and closer interaction with developers was a repeated theme, as was a desire for regulatory harmonisation. Across the system, the need for a UK reference laboratory and access to clinical samples for performance studies was also raised. The output will feed into the IVD Roadmap, and a report is being prepared.

Roundtable on *in silico* trials

2.6 The MHRA's Software & AI team and CPRD hosted a Roundtable on in silico trial (IST) approaches, to explore the benefits of these approaches to support the regulation of innovative medical products. The Roundtable brought together key stakeholders with subject matter experts. IST approaches use computer modelling and simulation and can be used both to optimise clinical trial designs by simulating medical product effects and safety in advance of human trials, as well as provide supporting evidence to address evidence gaps across the product life cycle. Potential patient benefits from IST approaches were discussed including how they could inform paediatric dosing, replace invasive aspects of clinical trials of implantable medical devices and to understand the effects of medical products in small populations (eg rare diseases), where a traditional trial may be underpowered.

PARTNERSHIPS

Multi Agency Advisory Service

3.1 The Multi Agency Advice Service is a cross-sector project between four core partner agencies, the MHRA, the Care Quality Commission, NICE and the Health Research Authority, to support development and widespread adoption of safe, innovative, value-adding data-driven technologies in health and social care. Funded by the NHS AI Lab, the project has 3 key objectives: understand the regulatory landscape covered by the four core partners and the challenges felt by stakeholders navigating it; develop a website to assist stakeholders in their journey; and integrate an advisory function for enquiries, which also serves as a feedback signal into the first two objectives. A new website will be accompanied by a staged communications initiative to slow down traffic to the site over time, allowing the agencies to manage feedback and enquiries. Website content for adopters of AI and data-driven products is also under development. Site branding is being updated to 'the AI and Digital Regulations Service'.

International guidelines

3.2 The International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) brings together regulatory authorities to develop guidelines to enable harmonisation. ICH Q12 is one such guideline, which will provide a framework to facilitate the management of post-approval chemistry manufacturing control changes in a more predictable and efficient manner across the product lifecycle, enabling

continuous improvement, reduction of regulatory burden and the resulting benefits to patients. We met with Health Canada to understand the outcomes of their ICH Q12 pilot project, which will help inform implementation by MHRA and a potential UK pilot project. It was also agreed that it may be beneficial if an Access Consortium group were established to share learnings from implementation across the consortium members and this will be proposed by the MHRA.

Access Consortium

3.3 As MHRA takes over the chairing of the Access Consortium (Australia, Canada, Singapore, Switzerland & UK), we are working to coordinate existing Access working groups and heads of agencies meetings to focus on discrete areas for progress over the next few months. This will include innovation, learning from Access partners' systems, and raising the international profile of the Access Consortium.

PATIENT SAFETY

Sodium Valproate

4.1 The Commission on Human Medicines (CHM) reviewed the available data on the risks associated with valproate on the male reproductive system and the potential for transgenerational effects. In light of the established and evolving risks of reproductive toxicity associated with valproate prescribing, the CHM has advised strengthening the existing risk minimisation measures and that greater clinical oversight is needed for both male and female patients under the age of 55 years. A separate working group has been convened to provide advice on the implementation of the strengthened regulatory measures in males on valproate.

Pholcodine

4.2 We announced on 14 March 2023 that, as a precautionary measure, pholcodine containing cough and cold medicines were being recalled from pharmacies and wholesalers. There was already a known risk of a very rare event of a serious allergic reaction (anaphylaxis) to muscle relaxants (neuromuscular blocking agents) during surgery following pholcodine use. However, following the emergence of new data and a comprehensive scientific review of the available evidence, the independent CHM advised that the benefits of these medicines no longer outweigh the risks. The Safety and Surveillance team worked with teams across the agency to issue the recall notice and a Drug Safety Update article to provide advice to healthcare professionals and patients to ensure clear and consistent information was available to patients.

Isotretinoin

4.3 Following the initial meeting of the isotretinoin implementation group, the report of the Commission on Human Medicines Isotretinoin Expert Working Group should be published shortly. The Isotretinoin Implementation Expert Advisory Group, which includes representation of the wider healthcare system in addition to healthcare professional representatives, has now been established to support the safe and effective introduction of the recommendations.

Pseudoephedrine

4.4 We are reviewing the evidence relating to the very rare risk of posterior reversible encephalopathy syndrome (PRES) and reversible cerebral vasoconstriction syndrome (RCVS) associated with medicines containing pseudoephedrine. PRES and RCVS have previously been identified as very rare potential side effects associated with pseudoephedrine containing products. The MHRA has issued a statement on this investigation and our review is ongoing. The European Medicines Agency's safety committee (PRAC) is also conducting a review of pseudoephedrine.

CPRD support for digitally enabled decentralised research

4.5 A CPRD co-authored publication (Aiyegbusi et al., 2022) in BMJ Evidence Based Medicine outlines how a digitally enabled decentralised approach offers an opportunity to open participation in clinical research to a much wider population and in settings that are more representative of the context within which interventions will ultimately be used. This paper included a patient representative co-author who led on the section on patient perspectives on site-centric versus digitally enabled clinical research. The paper showcases the Long Covid Study for which CPRD is supporting patient recruitment.

Criminal Enforcement Unit (CEU)

4.6 During February, the CEU strengthened its engagement with Border Force partners to explore opportunities for interoperability at the UK border. The medium-term aim is to raise the profile of falsified and unlicensed medicines at points of entry and increase interdictions. During February, the CEU's partnership with Border Force led to the seizure of almost 200,000 does of illegally traded medicines with an estimated value of more than £0.5 million. The unit is in the final stages of enhancing its technical capabilities to identify and deny access to criminal profits stored in cryptocurrency. Once in place, a project will commence to better understand and counter this aspect of the illegal trade in medicines.

Modified Vaccinia Ankara vaccine for Mpox

4.7 Scientists in Safety and Surveillance have been closely monitoring the safety of Modified Vaccinia Ankara (MVA) vaccine being used in response to the 2022 global mpox outbreak including in the UK. In February, the Commission on Human Medicines considered a paper on the available safety data on the use of MVA vaccine for mpox from the UK as well as data from the US, Australia and the Netherlands. The Commission agreed that no new safety concerns were raised for MVA vaccine from these data and that the benefit risk balance of MVA vaccine for mpox remained positive.

COVID-19 vaccines

4.8 Given the stable safety profile of the COVID-19 vaccines and the end of the Autumn 2022 booster campaign, the CHM has advised that the MHRA should transition to routine data publication and communication of safety concerns for COVID-19 vaccines. We published the last regular publication of the Summary of Yellow Card reporting for COVID-19 vaccines on 8th March 2023. As of 22 February 2023, we have received over 455,000 Yellow Cards for all COVID-19 vaccines, of which over 84% were received directly from patients, parents, carers and members of the public. As with all vaccines and medicines, the safety of COVID-19 vaccines is being continuously monitored.

Pharmacovigilance strategies

4.9 In early February, we presented an overview of our updated approach to patient safety, as a newly transformed agency, including the SafetyConnect programme and opportunities to enhance data collection at the Drug Information Association (DIA) Pharmacovigilance Risk Management Strategies Conference. We also presented our thinking on consideration for use of AI within pharmacovigilance processes and discussed the development of international best practice guidance.

DIGITAL AND TECHNOLOGY

Regulatory Management System (RMS) update

5.1 Progress on the RMS Project is good, and the team are focused on baselining a service implementation plan for Beta 1 to be launched in November 2023. The team are working in close partnership with Accenture on this. Digital design plans and governance are in place, and we are heading towards a clear architecture with platforms that will provide opportunities for service improvement and innovation going forward. A business readiness and launch plan (including communications) will be wrapped around the service implementation plan so that staff and industry are ready to use the new service. At the start of March, we held a webinar for industry to explain how the new system will help them and to outline the approach; this was attended by 672 industry members and there was excellent engagement during the webinar and feedback afterwards.

Agency data centre move

5.2 The Digital and Technology Group is on track to complete the relocation of the Agency's data and IT services to a new physical location in Hampshire by the end of March as planned. Over 70 per cent of the project is now complete and a plan is in motion to migrate the remaining core IT systems and Sentinel data over the coming weeks. An enormous amount of preparatory work has been completed ahead of this activity to minimise disruption to the Agency's core IT services and to ensure that performance is not impacted. This has involved a significant amount of collaboration across technical teams, a cross-Agency stakeholder group and external parties.

Laptop refresh

5.3 Following a successful pilot, the Laptop Refresh team has launched the roll out of new laptops replacing Lenovo laptop, which are now beyond economical repair. Our IT Helpdesk may not be able to provide technical support if users have a Lenovo hardware issue after 31 March.

DYNAMIC ORGANISATION

All Staff Meeting

6.1 February's All Staff Meeting represented greater collaborative working with the Staff Partnerships Group (SPG). The Internal Communications team worked with three representatives from the SPG to develop an engaging agenda. Outline topics for the meeting were shared with all staff in the agency well ahead of the meeting, enabling questions to be submitted in advance. Two separate, facilitated, panel Q&A sessions were held during the meeting for pre-submitted questions and for questions on the day. Chief

Officers located at both sites responded collectively and the extended opportunity to ask questions was well-received by our staff. Any questions not addressed during the meeting due to time constraints have since been follow up and published on INsite. Feedback indicates that staff appreciated and valued the updated format. The Internal Communications team will be building on this positive step forward for the next All Staff Meeting, currently planned for the second half of April.

Service transformation

6.2 Work is progressing on redesigned services for Established Medicines, Compliance, and Clinical Trials. Two new project managers have onboarded who are supporting Compliance, Established Medicines, Clinical Trials and Devices Regulation. The new Head of Strategic Change has also joined the Team and is starting to identify where change management is needed in each of the service areas.

Corporate Plan

6.3 A draft of the new 3-year Corporate Plan has been developed, including a significant stakeholder exercise to gain input from our key stakeholders. We held 18 meetings with patient representatives, industry groups and partners from health bodies and national/devolved government, and the DHSC. Overall, feedback was positive, and patients and stakeholders were pleased to be involved. Stakeholder feedback was also useful for the drafting of the Business Plan and wider ways of working and will be shared with relevant stakeholders. The draft Corporate Plan will be considered by the Board shortly and we expect to launch the Corporate Plan in April.

Graduate scheme

6.4 On 28th February we launched the MHRA's first in-house graduate scheme. For the pilot, we are seeking up to 8 high-potential graduates with a life sciences or biomedical sciences degree, or individuals with equivalent work experience, for a 3-year programme from September 2023. This will include rotations across our core operating groups and completion of the TOPRA Regulatory Affairs degree apprenticeship. Our aspiration is to broaden the scheme to all Agency groups for future cohorts. Our objectives are to build a pipeline of talent to develop into hard-to-recruit and specialist roles; to retain high performers beyond the scheme; and to introduce more structured career pathways from entry level. We also aim to increase the visibility of the MHRA as an employer of choice for graduates.

FINANCIAL SUSTAINABILITY

Fees

6.5 The first of the new legislation supporting the fees increase has been implemented and both sets should come into force during April 2023. This represents an important step towards achieving a balanced budget for 2023-24, and the creation of a new financial strategy. We have had some media interest following the publication of the new fees and our work with stakeholders throughout the process has supported what we are doing.

AGENCY PRIORITIES

In summary, the current priorities for the Agency are to:

i. Continue to lead in innovative scientific activities to cement the UK's capability as a world leader in research and development for innovative products;

ii. Continue to progress the redesigned services for Established Medicines, Compliance, and Clinical Trials;

iii. Progress the programme of work to improve the Agency's performance to deliver for our customers;

iv. Continue to monitor important safety issues such as pholcodine, sodium valproate, and pseudoephedrine, to ensure we address any patient safety issues swiftly and proportionately;

v. Focus on initiatives such as the graduate training scheme to attract skilled staff to the Agency and increase the visibility of the MHRA as an employer of choice for graduates and highly skilled candidates.

Dr June Raine, CEO
March 2023

Medicines & Healthcare products Regulatory Agency

BOARD MEETING HELD IN PUBLIC

21 March 2023

Title	**What was the financial and people performance of the MHRA for the year up to 31 January 2023?**
Board Sponsor	Rose Braithwaite
Purpose of Paper	Assurance

What was the financial and people performance of the MHRA for the year up to 31 January 2023?

1. Executive Summary

1.1 The operational surplus up to the end of January is £5.9m year-to-date (YTD), compared to a budgeted surplus of £0.2m. This is mostly the result of an underspend of £10.7m on staff costs as we have had slower recruitment into the new structure and higher staff exits than anticipated. The lower staff resource has consequently led to reduced Agency income.

1.2 When considering the total spend against funding, the Agency is showing an underspend YTD of £12.8m compared to a budgeted YTD surplus of £3m. In addition to the operating surplus this is due to a £4.1m underspend against our change funding, some of which is due to phasing. Spend on redundancy costs is forecast to be below budget. Work on both the Regulatory Management System (RMS) and investment at our South Mimms site have increased as forecast in Q4 and we expect the underspend against change funding to reduce to £1.3m by the end of the year.

1.3 Our customer debt has continued to improve. The focus on resolving debt over 6 months has enabled us to reduce it by £1.5m and bring it down from 38% to 27% of overall debt.

1.4 The people resource within the Agency is critical in terms of capability, capacity, quality and ultimately to Agency performance on both patient and business/financial outcomes. We have been making a concerted effort to recruit into the new structure and are finally seeing the benefits of this with a vacancy rate that has fallen to 12%.

2. Proposal

WHOLE AGENCY PERFORMANCE

Income

2.1 Year to date (YTD) income is £125.9m, £4.7m (4%) below budget (see table 1 below). There are two principal reasons for the lower income. Firstly, at the start of the year we increased the income due to the volumes of work in Healthcare Quality & Access (HQ&A) which needed additional resource to deliver. These extra staff took longer to recruit than planned. Although they are now largely in place the longer lead time has impacted fee income. Secondly is lower than budgeted sales of products by Scientific Research and Innovation (SR&I) due to reduced demand.

2.2 The income position against budget is forecast to improve by year end to a 3% deficit mainly due to a rise in Periodic Fee income from National marketing authorisations after the UK exit from the EU. This is now forecast to be around £3m higher than budget. This income is then allocated out to the fee-earning operations groups, where the services that it pays for are provided, in Healthcare Quality and Access and Safety and Surveillance.

Table 1 - Whole Agency financial performance to the end of January 2023

February 2023	**This YTD Actual £M**	**This YTD Budget £M**	*Variance vs Budget %*	**This Year Forecast £M**	**This Year Budget £M**	*Variance vs Budget %*
Trading Income	102.1	106.8	(4%)	122.9	128.1	(4%)
Income from DHSC	23.8	23.8	0%	27.5	27.5	0%
TOTAL INCOME	**125.9**	**130.6**	**(4%)**	**150.4**	**155.6**	**(3%)**
Staff Costs	64.5	75.2	14%	77.9	90.5	14%
Operating Costs	55.5	55.2	(1%)	71.8	66.5	(8%)
TOTAL EXPENDITURE	**120.0**	**130.4**	**8%**	**149.7**	**157.0**	**5%**
OPERATING SURPLUS / (DEFICIT)	**5.9**	**0.2**		**0.7**	**(1.4)**	
Spending Review Revenue	5.8	5.8	0%	7.0	7.0	0%
CPRD Revenue Funding	1.0	0.0		1.5	0.0	
TOTAL EXTRA REVENUE FUNDING	**6.8**	**5.8**	**17%**	**8.5**	**7.0**	**21%**
Staff Costs	0.0	0.0		0.0	0.0	
Change Costs	7.1	6.2	15%	8.8	6.5	35%
TOTAL REVENUE CHANGE COSTS	**7.1**	**6.2**	**15%**	**8.8**	**6.5**	**35%**
TOTAL REVENUE SURPLUS / (DEFICIT)	**(0.3)**	**(0.4)**		**(0.3)**	**0.5**	
Spending Review Capital	8.7	8.7	0%	10.4	10.4	0%
DH Capital Funding	5.0	5.0	0%	7.0	7.0	0%
TOTAL EXTRA FUNDING	**13.7**	**13.7**	**0%**	**17.4**	**17.4**	**0%**
Staff Costs	2.1	0.0		0.0	0.0	
Change Costs	3.3	10.5	69%	12.9	16.6	22%
CPRD Change Costs	0.9	0.0		1.5	0.0	
TOTAL CAPITAL CHANGE COSTS	**6.3**	**10.5**	**40%**	**14.4**	**16.6**	**13%**
TOTAL CAPITAL SURPLUS	**7.4**	**3.2**		**3.0**	**0.8**	
TOTAL SURPLUS / DEFICIT (incl. REVENUE & CAPITA	**12.8**	**3.0**		**3.4**	**(0.1)**	

Staff Costs

2.3 Staff costs are £10.7m YTD (14%) under budget due to staff vacancies within the Agency.

2.4 We originally budgeted for vacancies to improve from 13% in Q1 to 8% from Q2 and the remainder of the year as we completed transformation. The vacancy rate remains above that at 12% resulting in a further underspend in January of £0.9m on staff costs.

Change Costs

2.5 Change costs are currently £4.3m YTD under budget (revenue spend £0.1m under and capital spend £4.2m under), driven by YTD underspends in transformation, the South Mimms Capital Programme, redundancy, and the Regulatory Management System (RMS). Although change spend will accelerate in February and March, we are still forecasting a Full Year £1.3m underspend against budget.

2.6 Spend on RMS, now £2.1m underspent against the YTD budget, will pick up following the completion of the discovery phase but is still forecast to end the year £1.4m underspent.

Capital expenditure

2.7 We have £6m of baseline capital funding from DHSC to support the capital requirements of our South Mimms site. Of this we have spent £1.92m YTD but are forecasting to spend the full budget by the year end. Profiling the capital spend to the last quarter of the year mirrors the same pattern of spend as last year, so is considered realistic. We have developed a robust pipeline of the capital requirements at South Mimms for next year to ensure that we can commission and start work earlier.

2.8 We were awarded £9m of capital as part of the Spending Review to start work on the new Regulatory Management System (RMS). Of this we have spent £3.8m YTD. We plan to increase spend significantly in the last months as resources ramp up following completion of the discovery phase but we expect a £1.4m underspend by year end.

Customer Debt

2.9 The table below shows the Agency had debt of £11.5 m owed to it at the end of January. This has reduced by £0.3 m from the balance reported to the Board for December.

Table 2 - Aged debt as at 31st January 2023

Days since invoice	Amount	% of Total
0-30	4,300,419.70	37%
31-60	2,893,598.30	25%
61-90	998,749.48	9%
91-180	301,196.07	3%
181-365	1,691,402.51	15%
365+	1,346,295.85	12%
Total Debt	**11,531,661.91**	**100%**

2.10 The highest priority during January has been to reduce debt over six months old with the aim of clearing it before year end. The team have made good progress and have reduced it by £1.5m. This means that the percentage in this category has dropped from nearly 38% to 27% during the month. Further progress has been made during February with debt over 6 months old reduced by a further £1.3m to £1.7m in total.

People Performance

2.11 Recruitment continues at pace with 117 campaigns for 178 posts run in Q3 with 156 'true vacancies' as at the end of January, a reduction of 21 compared to December. The vacancy rate has now dropped to 12% compared to 19% in October. 79 new starters were welcomed into the Agency in Q3 and a further 45 are working their notice to join at a later date (this can vary from 1 month to 3 months, depending on sector and seniority) in Q4. Pre pandemic/transformation, the Agency typically recruited 150 roles per year on average.

2.12 There has been a further reduction in our turnover of staff to 16% bringing turnover closer to the levels considered 'healthy' by the CIPD (10-15%). Despite a challenging employment market for all sectors, we continue to see an increase in the number of joiners versus leavers, reflected in our decreased turnover and number of vacancies overall. We had 27 new joiners in January versus 8 leavers.

2.13 There were promising signs in the 2022 People Survey in respect of retention, with 66% of respondents (70% of staff) reporting they planned to remain working for the Agency for the next 1-3 years, an increase from the 59% reported in the 2021 survey. It is reassuring that as turnover reduces, the people survey gives us additional positive data in terms of staff intentions.

2.14 Sickness absence is currently at 7.4 days per FTE, a slight increase on the 7 days previously reported. The highest reported reason for sickness absence in the last quarter was Stress, Depression & Anxiety. Long term absence (any absence 20 days+) accounts for 59% of absence.

2.15 We are actively supporting staff to minimise sickness absence and improve health and wellbeing through occupational health and utilising our new Employee Assistance Programme. We also have mental health first aiders, related policies and procedures, training for line managers and staff, a focus on wellbeing (we participated in the MIND Wellbeing Index for example) and signposting to our toolkit of wellbeing resources. The Civil Service average absence is 6.1 days (from a range of 1.1 to 9.7 days reported).

GROUP PERFORMANCE

2.16 This financial year we have set budgets for Chief Officers of the three fee-earning operational groups for income and expenditure. The costs of the non-fee earning Groups are being tracked and managed by their respective Chief Officers. The approach to allocating these costs to the fee-earning operational groups has been revised to align to the new structure of the Agency. It has now been included in the reporting at group level.

Science, Research and Innovation

January 2023	**Period Actual**	**Period Budget**	*Variance vs Budget %*	**YTD Actual**	**YTD Budget**	*Variance vs Budget %*	**Full Year Forecast**	**Full Year Budget**	*Variance vs Budget %*
Scientific, Research and Innovation									
Total Staff (FTEs)	243	292	(17%)						
Total Income (£M)	4.3	4.7	(8%)	43.2	47.3	(9%)	52.1	56.7	(8%)
Total Costs (£M)	1.5	2.0	24%	17.2	19.6	12%	21.3	23.5	9%
Total Operating Surplus (£M)	**2.8**	**2.7**	**3%**	**26.0**	**27.7**	**(6%)**	**30.8**	**33.2**	**(7%)**
Corporate Recharge (£M)	3.0	2.8	(8%)	25.6	27.6	7%	33.5	33.2	(1%)
Total Surplus/(Deficit) (£M)	**(0.2)**	**(0.1)**		**0.4**	**0.1**		**(2.7)**	**(0.0)**	

2.17 Science, Research and Innovation (SR&I) is £4.1m (9%) below their YTD Income budget. This is mainly due to lower than budgeted income from the Sale of Goods and Services which include reference materials, contract filling and control testing. This year's results are significantly down on last year because there was no change in the flu strain, leading to fewer sales of flu reagents, and the loss of key contracts.

2.18 Operating Expenditure is £2.4m YTD below budget due to lower staff costs (£1.1m) from vacancies, and lower laboratory costs reflecting lower laboratory income generating activity. After adding the corporate recharge, which are £2m YTD underspent, the position is of a small YTD surplus of £0.4M.

2.19 The full year position forecast is of a total deficit of £2.7m. Although direct costs are forecast to be under budget, the deficit is driven by a £4.6m underperformance of income compared to the full year budget.

Healthcare Quality and Access

January 2023	Period Actual	Period Budget	*Variance vs Budget* %	YTD Actual	YTD Budget	*Variance vs Budget* %	Full Year Forecast	Full Year Budget	*Variance vs Budget* %
Healthcare Quality and Access									
Total Staff (FTEs)	349	365	(4%)						
Total Income (£M)	3.3	4.4	(24%)	42.0	44.4	(5%)	51.5	53.3	(3%)
Total Costs (£M)	2.5	2.7	5%	23.8	26.4	10%	28.3	31.7	11%
Total Operating Surplus (£M)	**0.8**	**1.7**	**(55%)**	**18.2**	**18.1**	**1%**	**23.2**	**21.6**	**8%**
Corporate Recharge (£M)	2.7	1.9	(46%)	17.9	18.1	1%	22.8	21.9	(4%)
Total Surplus/(Deficit) (£M)	**(1.9)**	**(0.2)**		**0.3**	**(0.0)**		**0.4**	**(0.3)**	

2.20 The overall position for Healthcare Quality and Access (HQA) is forecast to be close to budget at year end. The YTD surplus of £0.3m is forecast to change slightly to £0.4m by year end as the income position improves. This reflects increasing capacity in income generating teams and a rise in allocated income from the periodic fee.

2.21 HQA is £2.5m (6%) behind its YTD Income budget. Much of that is due to underperformance in Complex and Standard Applications income, although both have seen significant increases in deferred revenue indicating demand is not decreasing. Inspections income is also slightly behind budget. The high number of vacancies for much of the year is the driver for this. Most other income generating areas are performing well.

2.22 Income budget targets agreed at the start of the year had over-optimistic estimates of lead times for recruitment, training and staff turnover before new teams could achieve their full delivery potential. The lesson is, that for resources to have a full year impact on income, decisions need to be made well ahead of the start of the year. Following training of new staff, we expect the income run rate to increase in the final two months of the year.

2.23 In terms of YTD expenditure, HQA continues to underspend because of the impact of staff vacancies on costs. Travel and subsistence costs are also lower than budgeted in the Inspections teams because of vacancies and fewer international inspections. Lower allocated costs also contribute to the overall YTD underspend.

2.24 In recent months, recruitment to key roles across teams has improved and HQA will start 2023/24 with a more fully resourced team which will lead to higher income levels.

Safety and Surveillance

January 2023	Period Actual	Period Budget	*Variance vs Budget %*	YTD Actual	YTD Budget	*Variance vs Budget %*	Full Year Forecast	Full Year Budget	*Variance vs Budget %*
Safety and Surveillance									
Total Staff (FTEs)	263	306	(14%)						
Total Income (£M)	3.4	4.3	(21%)	44.1	43.8	1%	54.9	52.5	5%
Total Costs (£M)	2.2	2.3	7%	19.3	22.8	15%	23.9	27.4	13%
Total Operating Surplus (£M)	**1.2**	**2.0**	**(37%)**	**24.8**	**21.0**	**18%**	**31.0**	**25.1**	**24%**
Corporate Recharge (£M)	2.5	1.6	(51%)	16.0	16.0	0%	19.9	19.2	(4%)
Total Surplus/(Deficit) (£M)	**(1.3)**	**0.4**		**8.8**	**5.0**		**11.1**	**5.9**	

2.25 Safety and Surveillance (S&S) income is 1% ahead of its YTD budget because of higher Variations and Grants income, as well as higher than expected allocated income from the Periodic Fee. These income streams make up for lower than budgeted income in CPRD.

2.26 Total YTD Costs are 12% below budget, mainly because of a significant underspend on staff costs resulting from the high number of vacancies across most teams. However, recent recruitment along with the use of fixed term and contingent labour to tackle the workload has meant a slight increase in staff spend over the last months of the year.

2.27 YTD Non-Pay costs are slightly over budget, driven by high IT costs spend in CPRD due to unexpectedly higher inflation-related increases and the falling value of the GB Pound against the US Dollar for Azure services. As forecast, Patient Safety Monitoring spend on Contracted Out Services has increased over the last few months as the team has more capacity to dedicate to planned projects.

2.28 In the last months of the year, we forecast costs to remain around the current run rate and for the income surplus to increase because of higher staff capacity and the periodic fee. This leads to a significant forecast overall surplus of £11.1m, compared to a budgeted surplus of £5.9m.

Non-fee earning Groups

January 2023	Period Actual	Period Budget	*Variance vs Budget %*	YTD Actual	YTD Budget	*Variance vs Budget %*	Full Year Forecast	Full Year Budget	*Variance vs Budget %*
Non-Fee Earning Groups									
Total Income (£M)	3.9	1.5	170%	17.0	14.5	17%	17.4	17.4	0%
Total Costs (£M)	8.3	6.3	(32%)	59.8	61.7	3%	76.2	74.3	(3%)
Total Operating Deficit (£M)*	**(4.4)**	**(4.8)**		**(42.8)**	**(47.2)**		**(58.8)**	**(56.9)**	

* Non-fee Earning Groups' Costs are allocated to Fee Earning groups and appear as Corporate Recharge in the tables above.

2.29 We have a number of non-fee earning groups which directly support our three fee-earning groups. These are the Partnerships, Digital & Technology, Enablement and Corporate Groups.

2.30 The income received includes interest on our bank balance, which is higher than forecast because of rising interest rates, and DHSC change funding received as part of the Spending Review.

2.31 The expenditure of Non-fee Earning Groups is recharged to Fee Earning Groups. YTD Spend is 3% below budget. This is because of significant underspends in Digital and Technology, partially off-set by overspends on Accommodation costs because of delayed take up by Health Education England of office space in 10 South Colonnade. Expenditure includes the writing down of the fit-out costs for office space on the Ground, Fifth and Tenth Floors at Canary Wharf which we have vacated.

2.32 Total costs are forecast rise by year end as Digital and Technology spend increases.

3. Recommendation

3.1 The Board is requested to note the updated report on Finance and People Performance.

Rose Braithwaite
March 2023

Medicines & Healthcare products Regulatory Agency

BOARD MEETING HELD IN PUBLIC

21 March 2023

Title	**What are the proposed financial budgets for 2023/24?**
Board Sponsor	Rose Braithwaite
Purpose of Paper	Approval

What are the proposed financial budgets for 2023/24?

1. Executive Summary

1.1 The Executive Committee has developed a proposed budget for 2023/24.

1.2 This includes income of £162.3m, a 9% increase from last year from regulatory and trading activities. It includes total operating costs of £154.3m, a 6% increase from last year which leads to a £7.3m operating surplus. This will be invested during the year in projects to improve the quality and range of MHRA's services.

1.3 The budget is recommended to the Board with a deficit for the year of £0.1m . This is a very low risk position and will be managed during the year so that our expenditure does not exceed our income.

1.4 Capital investment of £25.5m is being sought from DHSC to invest in new digital systems to replace our core legacy casework systems and improve other digital systems.

2. Introduction

2.1 The MHRA is an Executive Agency of the Department of Health and Social Care (DHSC). It earns fees and charges from its regulatory activities and the other services that it provides. It uses this to deliver its statutory and non-statutory services. MHRA also receives grant-in-aid from DHSC to support delivery of statutory services where the Agency does not have the legislative powers to levy fees.

2.2 All capital funding and non-cash expenditure (depreciation) requires budget from DHSC.

2.3 The table below (Fig 1) provides details of the proposed balanced cash resource budget and capital budget for 2023/24. As with the current year we will monitor spend closely each month through the management accounts and make judgements about whether to reduce or increase our expenditure in-line with our income.

Fig 1 Table showing proposed resource and capital budgets for 2023/24

Revenue £'000s	21/22 Actual	22/23 Budget	23/24 Budget
Trading Income	128,352	128,060	141,686
Income from DHSC	20,600	20,600	20,600
Total Income	**148,952**	**148,660**	**162,286**
Staff Costs	98,997	90,479	94,887
Operating Costs	53,739	55,506	59,414
Total Costs	**152,736**	**145,985**	**154,301**
Operating Surplus	**(3,784)**	**2,675**	**7,984**
Change Income	0	6,000	584
Change Costs	26,865	5,625	8,634
Change Surplus/Deficit	**(26,865)**	**375**	**(8,050)**
Total Surplus/Deficit	**(30,649)**	**3,050**	**(66)**
SR&I Capital	7,838	6,000	6,000
Other Capital	5,901	12,400	19,492
Capital	**13,739**	**18,400**	**25,492**

3. Proposal

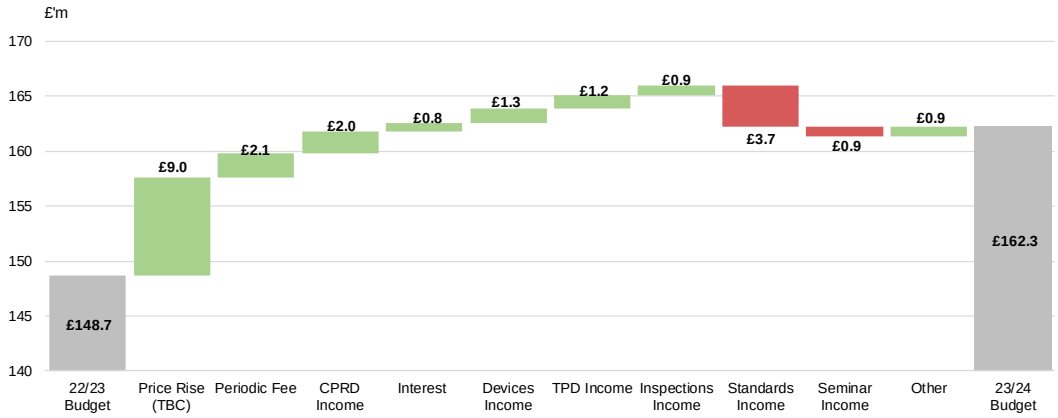
Income

3.1 The proposed trading income budget is £162.3m, an increase in income of £13.6m (9%) from last year (see chart 1 below). This is all driven by increases in our trading income.

3.2 The bulk of this increase (£10million) is from rises in our statutory fees of at least 10%. The two statutory instruments that implement this price rise are due to come into force on 1st April 2023. We are working through allocating the price increase across our income budgets. In the chart below it has already been allocated to inspections (c £0.9million) with the remainder shown separately.

3.3 The income from the medicines periodic fee increases by £2.1million before the new fee uplift is applied. We saw an upturn in this income stream during 2022/23 mainly due to an increase in the number of national market authorisations after the UK's exit from the European Union.

Fig 2 Chart showing movements in Income from 2022/23 budget



3.4 The Clinical Practice Research Datalink (CPRD) is projecting a £2million increase in income driven by a 10% price increase across all licenced subscription products and a growth in multi study licence holder clients.

3.5 We have increased the budget for devices income by £1.3m as the number and type of audits that we do has changed due to an increase in notified bodies for which we do this work.

3.6 The Agency is required to operate a registration system for nicotine e-cigarettes as part of the Tobacco Product Directive (TPD). Registration of these products increased in 2022/23 and we expect this to be sustained in 2023/24.

3.7 The largest reduction in our income year on year is for standard sales by £3.7million. This has been reduced to reflect a reduction of demand in Covid and influenza reagents which saw a peak of activity in 2021/22. We have already seen demand fall in the current financial year, so we are reflecting that in the budget proposals. Work will be undertaken this year to review all of the pricing in this area to ensure that processes are keeping pace with cost.

3.8 The grant-in-aid that the DHSC provides to support our legislative activities where we do not have the legal authority to raise fees or charges remains the same as in previous years. We will not have confirmation of this amount until later in March once our budget has been approved.

Staff costs

3.9 The Agency's staff costs include pay, employer's National Insurance and employer's contributions to the civil service pension scheme. The proposed budget of £94.9m is an increase of £4.9m (5%) from last year.

3.10 An element of the increase is for the annual pay rise, an assumption for which has been included. Every 1% pay rise increases costs by c£0.9m.

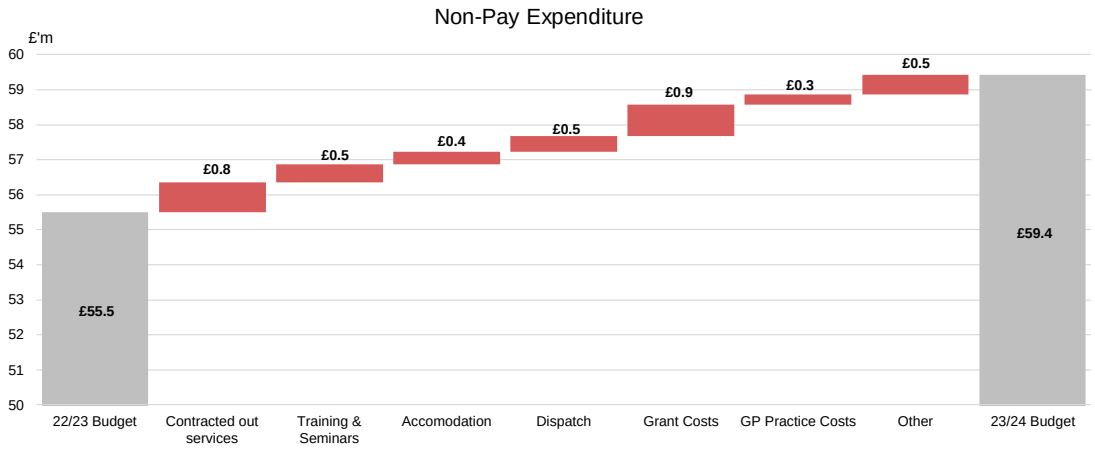
3.11 Staff numbers (FTE[1]) have increased in a small number of areas. Authorisation to increase FTE lies with the Executive Committee and is strictly controlled based on cost recoverability or an urgent delivery requirement. Where there is a peak of work, appointments are made on fixed term contracts. The increase of staff in this budget includes 8 additional roles for our pilot graduate scheme launched in February. These are fixed term contracts that run for 3 years with the ambition that the individuals, at the end of the scheme, will be in a good position to apply for vacant roles within our operating groups.

3.12 The costs have decreased by £2.9million due to an increase in our vacancy rate assumption. Last year we assumed an average vacancy rate of 9.25% across the year but have actually seen an average vacancy rate of around 17% due to slower than planned recruitment into the new Agency structure. This is the main reason why we are underspending in 2022/23 against our pay budget as we were too optimistic about how quickly we could complete our recruitment ambitions. To avoid this optimism-bias in 2023/24, we have increased our vacancy rate assumption to 11%.

Non-pay operating costs

3.13 The proposed budget of £59.4m is an increase of £3.9million (7%) from last year. The key movements in the budget proposals are in Chart 3 below.

Fig 3 Chart showing movements in Non-Pay operating costs from 2022/23 budget



3.14 Some of the cost increases that we are seeing in the proposed budget are due to rising supplier costs. This includes the cost of obtaining GP data that is increasing by £0.3million. It also applies to the increase in accommodation costs. These are budgeted to rise by just under £0.6m when we factor in the year-on-year savings of £0.2m[2] from the release of space on the 10th floor of the

[1] Full Time Equivalents

[2] In 2022/23 we removed rental costs for some of the 10th floor in anticipation of handing approximately 40% of it over to HEE. As a result, most of the savings were included in the 2022/23 budget. For the 2023/24 the office rental cost for the 10th floor has reduced by a further £0.176m.

Canary Wharf offices. Of this, half is due to rises in energy costs at South Mimms. Energy costs have gone up by £0.9m since 2021/22. We are working to mitigate this by installing additional solar panels which helps to both reduce our costs and our carbon footprint. The remaining increases are due to rises in prices for the security and service contracts and business rates.

3.15 The use of contracted out suppliers has increased in the Digital and Technology group. Some of this is to support additional maintenance work on the Agency's systems which we outsource. There are also new requirements under the Public Records Act relating to archiving records to the National Archive which we plan to outsource rather than grow in-house capability.

3.16 The increase in costs of training and seminars is driven by our undertaking to do more engagement work with our staff including on the new corporate plan. So, a proportion of this cost is to undertake more internal communication events and to have the right technical support to make hybrid events a success.

3.17 Grant costs have increased due to additional CPRD and Gates foundation grant activity. The increased costs are fully covered by income.

3.18 The £0.5m increase in dispatch costs is for our supply of standards that require transportation by specialist couriers. The increase is due to a mixture of increased volumes of packages and inflationary price rises. The increased costs will be recharged to customers.

Change resource costs

3.19 These resource costs (RDEL) cover the work that MHRA needs to do outside of its normal operational activities. The bulk of them are related to projects that will improve our services.

3.20 They include the resource costs necessary to deliver our capital projects. This includes just under £1m for the Regulatory Management System (RMS) project, c£0.1m for the SafetyConnect programme and £0.5m for CPRD systems (see para 3.26 – para 3.28 below).

3.21 We plan to invest £1.5m on the Yellow Card Biobank which is a biomedical database and research resource. Another £1.5m is being spent on access to an e-disclosure platform and legal support for public inquiry related work.

Capital expenditure

3.22 Since MHRA lost its trading fund status on 1 April 2022, we no longer have access to our reserves and all capital funding has to be provided by DHSC.

3.23 The retained reserves that we do still have access to, the residue of the joint working arrangement with the National Institute for Health Research (NIHR) to

support the set up and running of the CPRD, can only be used for resource change not capital investment.

3.24 As part of the transfer of the National Institute for Biological Standards and Control (NIBSC) into the MHRA, the DHSC committed to providing £6m of capital funding to maintain the science facility at South Mimms. We have a pipeline of capital investment on site that includes work on accommodation and the infrastructure across the site to maintain the laboratories and site security to ensure health and safety. Also, a rolling programme to replace the most critical scientific and health and safety equipment and investment to reduce our carbon footprint. In the past we have not always used all of the capital funding available to us. In order to ensure that we make full use of it in 2023/24 we have more work in our pipeline than we have funding for. However we will stagger our procurements and project timelines to ensure that this overprogramming does not result in an overspend.

Fig 4 Table of proposed capital investments in 2023/24

Capital	(£'000s)	Description
SR&I Capital	6,000	Various capital spend at South Mimms - detail provided in appendix. Total projected expenditure of £9.9m reduced by 39% for optimism bias
Safety Connect Programme	1,096	Ongoing Phase 2 of the new InformationTechnology programme - comprehensive and transformative programme of work which will improve the Agency's ability to proactively monitor and act on patient safety concerns across the full product lifecycle. This is an inflight programme launched in 2019 which will replace all legacy safety IT systems with a common platform for medicines, vaccines and devices
Regulatory Management System (RMS)	13,924	Replacement of legacy IT Systems -a modern and simple to use system optimising automation and digitisation for Agency users to reduce administrative tasks and improve efficiency; and a regulatory data platform
CPRD - IRSP: Scalability	980	Platform for team to manage clinical trials, integration with GPs. Business grown and not coping with volumes
CPRD - Trusted Research Environment	1,256	Allows customers to access data via cloud based data service. Legal requirement to move over next 3 years (Goldacre review)
CPRD - Website	156	CPRD website, essential to business - requires security updates, publish transparencies.
CPRD - Online Learning Platform	120	Part of governance to provide training for CPRD users - extension of website to be able to provide that. Will free up staff time.
CPRD - Customer Portal	300	Extension of website to allow clients single sign on point for CPRD - overview to link all systems together. Single point of access.
D&T Capital	1,660	Critical IT infrastructure inc laptops, on premises equipment. Risk is an operational, secruity and financial one, equate to loss of service.
Total	**25,492**	

3.25 We have requested additional capital funding from DHSC of £19.5m for 2023/24 to replace some legacy digital systems and improve others. The breakdown of funding between projects is in Fig 4 above.

3.26 The largest of these projects is for the development of RMS. We intend to invest c£14m in the RMS project started this year and is a critical part of MHRA's efficiency plans. It will update our core regulatory casework systems to provide

both new and improved regulatory processes for our staff and our customers, enable innovation, be sustainable from a cost, technology and resourcing perspective and allow the full decommissioning of all Sentinel and Lotus Notes legacy technology components.

3.27 We intend to invest just over £1m in our SafetyConnect programme which continues to be developed to give us the functionality to proactively monitor and act on patient safety concerns across the full product lifecycle. This is an inflight programme launched in 2019 which is replacing all legacy safety IT systems with a common platform for medicines, vaccines and devices. This includes the public facing Yellow Card system, which directly responds to the Cumberlege Review.

3.28 There are a number of upgrades planned to CPRD systems which will allow them to improve their offering to customers and scaled up to support additional customers to generate the higher income they have budgeted for in 2023/24.

Risks to the proposed budget

3.29 The final implementation of this budget does rely on grant-in-aid from the DHSC remaining as requested for both resource and capital funding. This will not be agreed until later in March.

3.30 The MHRA's trading income streams are demand-led and can vary year on year. We can see this particularly in standard sales which are impacted by the nature of the flu season each year. Often this variation is only known about later in the year. We have built the income budget using trends from a number of prior years and made conservative assumptions about the Agency's ability to deliver it.

3.31 The periodic fee is difficult to forecast precisely because it is calculated from companies' sales volumes in the previous year and is only finalised in the second half of the financial year.

3.32 The implementation of the new Fees order only applies to applications that arrive with MHRA from 1st April 2023. Any applications within our systems that pre-date that are paid for on the basis of the former fees orders. It will not be possible to model this impact until the end of the financial year when we know how many cases remain to be processed.

3.33 We have built in inflationary assumptions into our costs. However, we have seen more significant rises in inflationary impacts in 2022/23 than we were expecting, and this could occur again.

3.34 Our staff costs have an 11% vacancy assumption built into them to avoid optimism bias in budget setting. A 1% change in that assumption would lead to a c£1m increase or decrease in our costs.

3.35 All of these risks will be monitored during the year through our monthly management accounts and action taken where we are diverging from planned income or expenditure.

4. Recommendation

4.1 The Board is asked to review the proposed budget, consider the risks associated with it, and approve it.

Rose Braithwaite
March 2023

Medicines & Healthcare products Regulatory Agency

BOARD MEETING HELD IN PUBLIC

21 March 2023

Title	**What assurance can be provided by the Audit and Risk Assurance committee?**
Board Sponsor	Michael Whitehouse
Purpose of Paper	Assurance

What assurance can be provided by the Audit Risk and Assurance Committee?

1. Executive Summary

1.1. The Audit and Risk Assurance Committee (ARAC) met on Thursday 2 February 2023. This was Rose Braithwaite's first attendance as the MHRA's Chief Finance Officer. The Committee welcomed Rose and congratulated her on her appointment. ARAC thanked John Taylor for his contribution as Interim Chief Finance Officer.

1.2. We received a further update on progress in remedying issues raised by the Health and Safety Executive (HSE) at the South Mimms site. We considered how the Agency is responding to the recent independent Gateway review of the MHRA's transformation programme. We reviewed the Agency's nine-month period financial statements together with the likely full year position.

1.4. As two months remain of the current financial year, we spent some time in assessing the Agency's preparedness for ensuring that its Annual Report and Financial Statements will meet the agreed timetable for Board approval and laying in Parliament. This included a helpful paper demonstrating how the Agency had stress tested its timetable, together with updates from External and Internal Audit.

1.3. Normal standing ARAC agenda governance items included risk, complaints handling, any instances of reported fraud and whistleblowing.

2. Health and Safety Executive (HSE)

2.1. A review by the HSE in 2022 identified that the Agency was not compliant with a number of Health and Safety requirements in the laboratories at the South Mimms Site. A number of specific issues have been dealt with. However, meeting HSE's April 2023 deadline to demonstrate that the Agency has a clear approach for managing health and safety risks from organisational change is dependent on having key roles staffed with appropriate skills and we were assured that having such roles filled occurred prior to other activity allocations for staff. Retaining the Agency's SAPO (Specified Animals Pathogens Order) is similarly dependent on a key role been filled.

2.2. We were assured that the Agency is giving priority to addressing the HSE's recommendations, but it is taking longer than envisaged to fill posts. A new specialist recruit who had agreed to join the Agency in early January subsequently decided not to take up post. While a replacement has now been secured it will take several weeks for the individual to complete the necessary training.

2.3. We explored how the Agency ensures generally that health and safety remains a priority at the South Mimms laboratories. Other than for a small number of key specialist roles, the Science Research & Innovation (SR&I) Group does not have a dedicated Health and Safety team. All staff have responsibility for maintaining health and safety and to do so receive appropriate training and guidance. We believe that this approach and overall accountability could be strengthened by including health and safety in staff's annual personal objectives.

2.4. South Mimms is an old site and we were told that the need for further essential maintenance has recently become apparent.

2.5. While we were assured that the Agency is focused on implementing the HSE's recommendations, progress is slower than planned largely because of staff shortages. Health and Safety is included on the Agency's risk register. It remains a key issue requiring sustained leadership.

3. Gateway Review of Transformation Programme

3.1. The Agency commissioned an independent review of its transformation programme. The review was positive about aspects of the programme, but it emphasised the need for stronger governance and accountability arrangements and the importance of intended benefits being defined and tracked. The Organisational Development and Remuneration Committee (ODRC) has emphasised the importance of communicating a clear vision of the future so that all staff can buy into the programme and be committed to it. ARAC support this.

3.2 Like ODRC, we welcome the appointment of the new Director of Delivery who is also the Senior Responsible Officer for the transformation programme. ARAC discussed with him the extent to which new systems and business processes have been designed. It is clear that there is still significant work to do. We emphasised the importance of clear accountabilities for delivering this redesign being defined and agreed at all levels in the Agency. These should cover clear sustainable benefits and added value for patients and other MHRA stakeholders. But improved efficiencies in the form of reduced cost and/ or improved productivity in keeping with the principles of Managing Public Money also need to be planned for from the outset. Such cost improvements need to be built into budgets at the earliest practicable opportunity. We intend to revisit this given the challenges inherent in transformation and demonstrated previously.

4. Financial Performance

4.1. We reviewed the Agency's financial statements for the period up to 31 December 2022 together with the estimate of the year end at 31 March 2023. We welcomed the segmental presentation which demonstrates financial performance against each of the MHRA's core objectives and enhances external accountability.

4.2. As the Agency is no longer a Trading Fund, it is required to surrender any unspent funds. Overall, the Agency is spending less on pay because of the level of unfilled posts but this is compensated for partly by spend on consultants and staff on interim contracts. The Agency is nevertheless projecting a cash underspend. We were assured that Finance is managing this to ensure that the best value is achieved from funds allocated to support key priorities in the Agency's Delivery Plan.

4.3. We discussed and were assured as to Finance's plans to manage a number of accounting issues which are likely to be time-critical in meeting the Financial Statement's timetable. These include provision for any redundancies; valuation of outstanding processing backlog in terms of fees and debtor provision; securing necessary Cabinet Office and Treasury approvals as required; and regularity compliance particularly in respect of tighter central controls of interim and consultancy spend.

4.4. We considered a short paper, which we had asked for at a previous meeting, setting out current vacancy levels and where these were having to be compensated for by interims or consultancy support which are likely to be more expensive in the medium term. The highest level of vacancies are strategy and programme management with 42 percent of posts not filled by permanent staff; digital - 35 percent; and Safety and Surveillance - 15 percent. The MHRA is not alone across the public sector in facing a significant recruitment and retention challenge. We were assured that the Agency is adopting innovative approaches to attract staff but concerned this will remain insufficient. The scale of vacancies inevitably increases delivery risk for some key projects.

4.5. We discussed the Agency's longer-term approach to attracting and retaining talent. The proposal for the Agency and other health bodies to work together to provide better career development opportunities linked to the Government's Life Sciences strategy has considerable potential to enhance the attractiveness of joining the Agency. To be successful this initiative will require good project management and governance.

5. Risk Management

5.1. Progress in strengthening the Agency' s approach to risk management remains good. The Committee considered that all key risks were included but emphasised the need to focus on the Agency's added value contribution to the wider health system and consideration of whole system risk; realising the benefits of transformation at pace; implementation of the new Regulatory Management System (RMS) and the associated financial risk; and health and safety risk (paragraph 2,5).

5.2. The Committee emphasised the importance of the Agency having a clear articulation of what success would like if it is to be confident that its risk management is effective. Success criteria should include confidence of what constitutes risk and how to report it is understood by everyone in the Agency; risk appetite is clear and supports innovation and that risk management provides assurance that the Agency remains resilient.

5.3. The improvements which the Agency is making to its risk management will only have been in place for part of 2022-23. It is important that the Agency's Governance Statement sets out and provides assurance as to how risk was managed over the full financial year

6. Internal Audit

6.1. Progress in delivering the Internal Audit work programme is slower than planned. Of a planned programme of 9 reports only 3 have been completed plus a review of compliance with Cabinet Office Standards for financial control. Two reports on Patient Engagement and Managing Conflicts of Interest are close to completion. Four reviews about to start or being scoped are: cyber security; Regulatory Management System (RMS) governance; agency fees; and handling of the Agency work backlog. Of the three reports completed; one received moderate assurance and two received limited.

6.2. Over the last three years the Internal Audit programme has been more back ended with a significant proportion of work delivered in the last three months of the financial year or being slipped into the next financial year. It is important that more even delivery is achieved through the year so that the Executive and ARAC have sufficient time to consider Internal Audit findings and ensure that the value added from the implementation of recommendations is achieved. Both Internal Audit and the Agency acknowledge that they both need to improve the way the annual programme is delivered.

6.2. To provide its annual assurance to the Accounting Officer on the Agency's governance. Internal Audit needs to undertake a sufficient body of work. Delays can put this assurance at risk and have implications for the Financial Statements timetable. The Director of Internal Audit assured ARAC that if the remaining reports were completed as planned, he should have sufficient evidence on which to base his opinion. He also confirmed that Internal Audit had the staff scheduled to deliver the work as long as there was no slippage by the Agency in agreeing terms of reference and in responding to his findings.

6.3. ARAC will next meet on 21 April. The Committee agreed that Internal Audit Reports should be shared with ARAC as they are agreed with the Agency and not wait until the next formal meeting. The Chair of ARAC will now meet monthly with the Director of Internal Audit and the Chief Finance Officer to review progress in delivering the remaining programme.

6.4. ARAC was due to receive a progress report on implementing Internal Audit recommendations. This will now be circulated to the Committee by the end of February.

7. External Audit

7.1. External Audit are about to commence their two-week interim audit. This is as originally planned. External Audit confirmed that they would be undertaking more extensive pay roll testing in response to higher levels of errors which occurred last year. The Chair of ARAC will separately seek assurance on the outcome of the interim audit with the Chief Finance Officer.

8. Annual Report

8.1. We received and were assured by the detailed paper prepared by the Governance Team and Finance which stress-tested all the main key milestones in the Annual Report timetable. We discussed these at various points in the ARAC meeting focusing on potentially critical accounting issues (paragraph 4.3 above); governance (paragraph 6.2); risk (paragraph 5.3) together with advice from External and Internal Audit.

9. Governance

9.1. We received and were assured by a comprehensive paper on the Agency's handling of complaints. The number of complaints raised with the Agency has increased. Some of these relate to processing backlogs which the Agency is addressing. We asked if there was any systemic or underlying reasons motivating complaints or their increase. We were told that while the Agency's Customer Experience Centre analysed complaints and other correspondence there were no discernible themes. It is clear that since COVID more people are aware of the Agency.

9.2. We reviewed data on incidences of over-payments and non-regulatory fraud. There was no major incident of fraud. Over-payments were human resource related which is becoming a common occurrence. We understand that Human Resources plan to speak to managers to remind them of their responsibility to notify payroll of any changes. ARAC will return to this when it reviews progress in implementing Internal Audit's recent review of payroll for which it awarded limited assurance.

9.3. One instance of whistle blowing was brought to the Committee's attention. This is currently being investigated through the MHRA's governance processes.

10. Next meeting

10.1. ARAC will next meet formally on Friday 21 April.

Michael Whitehouse
Chair of the Audit and Risk Assurance Committee
February 2023

Medicines & Healthcare products Regulatory Agency

BOARD MEETING HELD IN PUBLIC

21 March 2023

Title	**What assurance can be provided by the Annual Health & Safety Report of the MHRA?**
Board Sponsor	Marc Bailey
Purpose of Paper	Assurance

What assurance can be provided by the Annual Health & Safety Report of the MHRA?

1. Executive Summary

1.1 The Agency carries out a wide range of activities and has a broad range of health and safety (H&S) requirements including safety of staff working in the office, at home, and in high-risk activities both on site at South Mimms laboratories and in off-site locations. There will always be a possibility of accidents and incidents taking place, and it is the responsibility of staff across the organisation, from the most senior leaders through to all staff working across the Agency, to take all requirements seriously to ensure that H&S regulations are not breached. For this reason, the Corporate Risk Register includes a risk that 'MHRA will breach H&S regulations' and requires the organisation to ensure that there is ongoing work and action taken to ensure this risk is mitigated as far as possible.

1.2. The year 2022-23 has been challenging and has resulted in pressure on the systems that ensure health and safety for the organisation. This has resulted in an increase in issues and incidents and subsequent actions to address them. This paper outlines some of the key pressures that have been experienced this year, but also provides an update on action that has been taken and the gradual move towards greater assurances that the risks are being reduced. The paper is supported by further information in the annual Health and Safety Report for 2022-23 and is provided with this paper.

2. Introduction

2.1. The 2022-23 Agency H&S report is the first report following an intense time experienced by the Agency during the later stages of the COVID-19 pandemic, and in undergoing a large-scale reorganisation. This report provides a summary of key areas of focus from the last year, and also highlights more work to be done as the Agency continues to settle from the reorganisation. This work will be delivered as planned steps in the continual improvement that is always required in H&S Management Systems.

2.2. The H&S team has focussed this year on managing the effects of changes in structure of the Agency following the Transformation that took place in early 2022. The H&S management system within the Agency is a model in which a small central specialised H&S team of 5 staff provides central management of H&S requirements in the form of advice on legal requirements, ensuring a robust framework and policies and procedures are in place for staff to work within, managing training, auditing, and leading investigations into accidents and incidents. Supporting the team is a network of staff across the Agency with additional health and safety responsibilities including, for example as local Safety Champions, risk assessors, investigators, fire wardens, and first aiders. In addition, for South Mimms, there are key safety critical roles supporting high risk activities such as radiation safety, biological safety including work under the Specified Animal Pathogen Order (SAPO). The benefits of this model, that has been commended by HSE, and

adopted by other organisations, is that health and safety understanding, and commitment is embedded within the workforce by those who carry out and understand the requirements for their work areas. The workload requirements for this model and ensuring the proportion of additional responsibilities does not increase risks for staff, is a key aspect of managing this model and particularly when changes occur. The process of Plan-Do-Check-Act is key for managing processes within the H&S Management System.

2.3. Following the reorganisation, a mapping activity took place to identify all safety critical roles in the organisation, and the H&S team has been working with Chief Officers and Deputy Directors to identify staff to take on these activities. In the region of 80% of safety champion roles are now filled and work is continuing with managers to ensure we are at 90% coverage by end of Q1 23/24 and we maintain at least at this level moving forward allowing for normal levels of staff changes. The interest from staff who have volunteered or agreed to take on these additional activities is encouraging and shows a positive attitude to health and safety within the organisation. For example, several staff have volunteered and are being trained for the Biological Safety Officer role which will be shared across a team to provide increased resilience and spread the workload. Active recruitment is also taking place for some vacant posts that have a large proportion of H&S in the role, e.g. SAPO4 BSO and Head of Engineering, and it is hoped to fill these roles by the end of Q1 23/24 but meanwhile interim cover is being managed for these roles.

2.4. The widespread changes in the organisation have required staff to undertake new training, whilst the COVID-19 pandemic, and then adoption of hybrid working resulted in a backlog of training for all staff. Training courses are now all back up and running and staff have been attending courses and being reminded of the need to ensure their mandatory training in health and safety is carried out. Measuring levels of training will be a KPI brought back in 23/24 to ensure there is full recovery in this area.

2.5. The Health and Safety Executive (HSE) Microbiology & Biotechnology Unit (MBU) carries out routine inspections throughout the year through an intervention plan and focusses on high containment areas. Its main focus in 2022-23 was on two key areas.

2.5.1. The first was around Management of Organisation Change and how this was carried out in relation to health and safety of staff and particularly in recognising safety critical roles and activities and measuring the impact on workload following changes. A formal letter was issued to the Agency requiring a review of the Agency policy on organisation change, and a review of management of roles related to supporting high containment areas. Many changes have been made to address the process that should be followed during organisational change in assessing the risks to the management of health and safety, and HSE have accepted the work carried out so far, with a final pulling together required in a revised policy on organisational change that is being developed and due for submission to HSE by the end of April 2023 to close the actions. The work on the management of roles related to high containment areas is now completed and closed by HSE.

2.5.2. The second area was to renew the licence held by the Agency for its work under SAPO for activities at levels 3 and 4. All requirements have been completed for the renewal at level 3 and the licence granted, and for level 4 the licence has been granted for storage whilst some final requirements are completed to work at SAPO4 level which is anticipated by Q2 23/24.

2.6. Other interactions this year with HSE have resulted from incidents reported under the Reporting of Injuries, Diseases and Dangerous Occurrences Regulations (RIDDOR). Two incidents were reported in February 2022 resulting in Improvement Notices requiring improvements to be made in the Agency's risk assessment policy as well as emergency procedures in high containment areas. Both improvement notices were successfully closed in 2022-23. Three further RIDDORS were reported, two in relation to autoclaves resulting in HSE issuing three verbal instructions which will be monitored through the normal intervention programme with HSE. The final RIDDOR, relating to a minor spill in a CL3 laboratory, was initially reviewed by HSE, and was downgraded to non-reportable due to the hazard group of the agent involved.

2.7. Progress on the activities above have been reported regularly this year to the Executive Committee, Audit and Risk Assurance Committee, and the Board, to ensure oversight and assurance throughout. In addition, an outstanding action at the start of the year was for leadership training and awareness for the Executive Committee (ExCo) and the Board, and this was delivered in the early part of the year. This resulted in a useful review of roles and responsibilities and led to the development of a more robust governance process for H&S reporting within the Agency. The HSE intervention plan for 2023/24 includes a review of 'Leadership and Safety Management System' in Q3 or Q4 of the forthcoming year.

2.8. Although the focus in 2022-23 has been very much the activities at South Mimms, the H&S team supports all health and safety requirements across the Agency. This has included staff who are based at Canary Wharf (10SC) and also those staff who are required to travel off site either within the UK or overseas. This part of the Agency was previously under the certification with BSI for ISO 45001, but a review of workload required to maintain this certification, and a drive to consider activities within the One Agency, led to a decision to move towards HSE's Managing for Health and Safety (HSG 65) programme for the whole Agency, which is the standard already embedded at the South Mimms site. Development of the unified programme is ensuring that the benefits from the previous compliance with ISO45001 are incorporated where appropriate.

2.9. At 10SC, the early part of the year saw a slow return of staff to work on site after the lifting of measures from the pandemic. The H&S team has contributed to work on future ways of working to consider safe methods of hybrid working and that appropriate measures and assessments are in place for staff working from home. This has led to input on the hybrid working policy developed by HR and now issued to staff with H&S advice included.

2.10. Also, this year, the Agency now has a smaller footprint of offices at 10SC, and this has required active management of changes by the H&S team to advise on layout and working practices. This has resulted in review of procedures for receipt of materials on site, and for storage arrangements and disposal of medicines and controlled substances.

The H&S team is working with regulatory colleagues to understand the Agency requirements and ensure full procedures are in place and risk assessments are up to date for these activities. The Dangerous Goods Safety Advisor has been involved in advising in this area. Completion for this work is targeted for the end of Q1 23/24.

2.11. Throughout this year we have seen a steady increase in activities off site, including a return by Inspectorate and Enforcement colleagues to site visits, and by staff attending more meetings and scientific conferences. Activities take place in the UK and overseas and the number of requests for travel has increased resulting in increased numbers of risk assessments for gradual changes to COVID-19 measures for different countries, and assessments of unrest in countries due to international instability. A review of requirements by the UK and Overseas Travel Working Group has resulted in update to the travel policy and procedure and approval process and the revised documents will be issued in Q1 23/24.

3. Proposal

3.1. Despite being a difficult year, the hard work by the H&S team and many staff across the organisation is showing a positive improvement and providing assurance that difficulties are being addressed. Work is continuous, and H&S management systems require continual review and looking at opportunities for improvement. For this reason, the H&S risk on the Corporate Risk Register should always be in place but many mitigating actions have been carried out this year and further actions are due for completion in early 2023/24. The work to lower the risks is continuous, and this is helped by the visible support from ExCo and the Board in helping to further develop a positive H&S culture across the organisation. The HSE has worked closely with the Agency this year and supported us in improving areas of weakness and making recommendations where required to strengthen our H&S systems.

3.2. The new governance process has allowed a clear reporting mechanism to be adopted and has included a faster escalation route when needed to address any urgent issues. This has resulted in greater recognition of the importance of H&S management and shown the H&S team and all staff that it has the support of the senior management of the organisation for the health and safety and wellbeing of staff. Clear publication of this to staff will further help ensure staff feel supported by a robust H&S system.

3.3. The annual report provides a high-level summary of activities and an overall level of assurance. It is proposed to use the regular reporting process to review specific topic areas in more depth as part of a cycle of reporting to ExCo, Risk Assurance Group and Audit and Risk Assurance Committee, so that some of the detail behind the very wide-ranging H&S responsibilities are understood more. Areas of interest can be flagged to the team for future inclusion.

4. Recommendation

4.1. It is recommended that the Board recognises the good progress made in 2022/23 to improve the H&S Management System within the Agency following a time of significant change and that it recognises the immense support by staff to ensure continuous improvement.

Marc Bailey
March 2023

Health & Safety Annual Report 2022-23

A comprehensive review of the Agency's H&S performance during 2022-23

Published March 2023

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1.0 Introduction

The Annual Health & Safety (H&S) Report for the Agency provides an overview of the progress made against planned objectives, Key Performance Indicators (KPIs), Safety Performance Indicators (SPI's) for high hazard areas and other relevant activities for 2022-23. From this report, and with recommendations from the Executive Committee (ExCo) and the Agency Board, priorities for the forthcoming year can be identified.

Objective setting for the year was based mostly around the work needed following the reorganisation of the Agency resulting in staff changing roles and major changes in ways of working. In addition, much of the year has required focus on addressing requirements highlighted by the Health and Safety Executive (HSE) through the planned intervention programme and responses to incidents.

The H&S team sits within the Science, Research and Innovation Operating Group of the Agency and provides the H&S support for the full Agency. The team is small and relies on a network of support roles across the organisation to provide management of specific work activities and champion roles to support staff locally in their groups. Due to transformation, many of the staff in these roles have changed and additional training is being undertaken to new staff who have taken on these activities. These support roles are essential in ensuring a robust health and safety environment and culture within the organisation and these staff are thanked for their commitment to these roles. The main team has been at full complement for the most part of the year following successful recruitment campaigns.

2.0 Summary Report

In 2022-23 the Agency has reviewed H&S objectives and priorities as a result of the planned organisational changes and placed several projects on hold. The information below shows the progress made against planned objectives:

2.1 Leadership

There have been significant organisational changes across the Agency over the past year, however, the focus on H&S priorities has been maintained and subject to review by external regulators.

The objective for visible H&S leadership by Senior Management was met in several ways:

- As part of the Agency Transformation, the H&S team was moved into a new Function designated to Health and Safety and Quality Assurance. It was recognised that leadership of this new Function should focus in particular on these two areas and the role of Deputy Director for H&S and QA (HSQA) was put into the new designed organisation structure.
- Marc Bailey (Chief Scientific and Innovation Officer and H&S Champion) and Marie Donatantonio (Deputy Director, HSQA) have attended planned Health and Safety Executive (HSE) interventions.
- As part of the wider UK responsibilities for H&S, both are members of the national Biosafety Strategic Leadership Group which meets quarterly with similar UK Agencies and organisations.

- The HSE Annual Review meeting in May 2022 was attended by senior leaders including Chief Executive Officer, June Raine.
- The Executive Committee (ExCo) has supported health and safety initiatives related to changes to ways of working through various committees and working groups.
- ExCo and Board members underwent specific H&S training particularly focused on their roles as senior leaders of the organisation and have followed this with active interest and monitoring of health and safety risks and activities via regular reporting by the H&S team.
- H&S governance and reporting arrangements have been reviewed to ensure a mechanism for routine reporting as well as for urgent escalation.
- The ExCo/Board Champion for health and safety for the Agency continued to support H&S initiatives and provide a strong link between Centre H&S committees, the Health & Safety Strategy Group (HSSG) and ExCo.
- MHRA was not inspected through the HSE planned intervention programme this year for H&S Leadership, though an action was completed for delivery of H&S Leadership training to the Health and Safety Champion and Agency Board. A revised Agency governance structure for H&S reporting has been introduced and the HSE intervention plan for 2023/24 will include a review of 'Leadership and Safety Management System' in Q3 or Q4 of the forthcoming year.
- The Agency's risk register has been updated to reflect the impact of the organisational structure changes during transformation stages and early delivery.

2.2 Health and Safety Strategy

Further revision of the draft 5-year H&S strategy setting out the Agency's vision for Health, Safety and Wellbeing over a 5-year period has been put on hold this year whilst the Agency settled into its new structure and ways of working. The draft strategy is however being followed with its seven key strategic themes being used as the key headings for the H&S Action Plan, and this will be progressed next year in line with Agency governance changes and will be consulted on and finalised for approval through ExCo and the Agency Board.

2.3 Coming out of Coronavirus pandemic

The early part of the year as the restrictions following the pandemic were lifted, H&S provided input for the continued return of staff to the Agency sites and the development of hybrid ways of working. Contributing to the discussions at the Future Ways of Working Group, the H&S team have provided input to the home working and hybrid working policies and have worked on the continued re-opening of the sites to allow staff to work under these new models.

2.4 High hazard activities

A review of Biological Safety Data Sheets (BSDSs) has been carried out through the Containment Level 3 user group (CL3UG) and these documents have been submitted to the Biological Safety Sub-Committee (BSSC) for approval, prior to full implementation of this system. The BSSC has provided feedback regarding the BSDSs (mainly around consistency) - once these final changes have been made by the CL3 UG, the BSDSs will be approved and uploaded onto the Safety Organiser system for risk assessors to use. BSDSs will ensure consistency and best practice when staff undertake Biological Risk Assessments.

Mapping of safety critical roles was undertaken across the Agency to identify all relevant roles within the organisation, and monitor the progress being made in ensuring these roles are filled. This has

become a continuous process, and the list of roles is reviewed each quarter as part of the KPI review. The mapping of roles has been developed further to take into consideration HSE feedback from a management of organisational change inspection. The impact of changes to any of these critical roles must be considered during the planning of any future transformations. The resource, training and time to get new staff trained in these safety critical roles is significant. Examples of these key roles include Safety Champions, risk assessors and roles required to support high containment activities such as Biological Safety Officers (BSOs) and Specified Animal Pathogen Order (SAPO) BSOs. Progress is being made to obtain suitable staff to fill these roles. At Q3 reporting for example, several staff have volunteered and are being trained for the Biological Safety Officer role which will be shared across a team to provide increased resilience and spread the workload. Safety champion roles are approximately 80% in place by the end of March 2023, the outstanding gaps have been reviewed to ensure there are no critical risks, and recruitment campaigns are underway for specific roles that have a high health and safety element, e.g. SAPO4 BSO and Head of Engineering. It is expected to complete filling these roles by end of Q1 23/24 but meanwhile interim cover is being managed for these roles. The H&S team works closely with managers to ensure the health and safety requirements and level of workload is understood, and to ensure activities are included in the post holders' job descriptions and goals, where applicable.

Significant improvements have been made in risk assessment procedures to ensure that the review process is robust, and controls selected are both effective and reliable. The Risk Assessment Policy has been updated to include an independent (wider team) review of risk assessments for high containment activities. Improvements have been made to the H&S database Safety Organiser to ensure the rationale for risk control selection is clearly recorded and available for future reference. The updated draft policy has been through consultation and the final version is due to be approved. The H&S Team will be delivering specific workshops to update all risk assessors and authorisers of the changes. The Risk Assessor Training module has also been updated.

Improvements in emergency procedures have also been made to ensure that all high containment areas have a clear strategy and schedule for reasonably foreseeable scenarios which may occur based on each area's work activities. This is being progressed through the CL3UG.

The South Mimms site requires the safe use and management of containment facilities. It is essential to ensure these are maintained to the required standards and ongoing review and improvement is achieved through the oversight of the H&S team and the Biological Safety Officers (BSO). User requirements for these facilities are reviewed through H&S committees allowing staff and Trade Union input. The South Mimms Project Team are managing future projects which will mitigate health and safety risks associated with loss of power and potential loss of containment in high hazard facilities. A programme of work is in place for the SAPO4 facility to ensure compliance with the SAPO requirements and compliance is monitored through Safety Performance Indicators.

A programme of biosafety audits is in place to monitor compliance across all high hazard facilities. These audits are carried out by the H&S Team with input from the Biological Safety Officers.

2.5 Health and Safety Executive (HSE)

The HSE planned intervention inspections provide the external review of the management procedures. A regular and open dialogue is maintained with HSE on any questions or concerns that may arise through the year.

Two main inspections were planned for 2022/23 related to particular areas of focus for this year. The first was a topic-based inspection on 'Management of Change – Organisational Restructure'. The second was an inspection to prepare for the licence renewal of our work under the Specified Animal Pathogens Order (SAPO). Both inspections resulted in a great deal of work to address findings.

The Agency received two improvement notices following two Reporting of Injuries, Diseases and Dangerous Occurrences Regulations (RIDDOR) reportable incidents in February 2022. The notices required improvements to be made in the Agency's risk assessment policy as well as emergency procedures in high containment areas. Both improvement notices were successfully closed in 2022-23.

A dangerous occurrence was reported under RIDDOR, relating to work carried out by a specialist autoclave contractor. The outcome of the HSE investigation resulted in verbal enforcement, in relation to control of contractors.

2.6 Accidents and Incidents

RIDDOR reportable incidents – there were 3 RIDDOR reportable incidents in this financial year at South Mimms. All were reported as Biological Dangerous Occurrences under RIDDOR. Two incidents relating to autoclaves were investigated by the HSE, and the Agency received three verbal instructions as a result. The final RIDDOR, relating to a minor spill in a CL3 laboratory, was initially reviewed by HSE, and was downgraded to non-reportable due to the hazard group of the agent involved.

Overall trend analysis for the past 5 years indicates a general decrease in accidents and incidents at both sites. At South Mimms the number of incidents (including near misses) remains proportionally higher than the number of accidents over the five-year period, indicating a healthy reporting culture is being maintained. The number of accidents and incidents reported at 10SC, remains lower than at South Mimms, a reflection of the different environment.

There are no significant trends identified, but further work in improving categorisation of incidents is still required as reporting as 'unknown' or 'incident' or another type of accident' does not support trend analysis. The H&S Team will continue to work with Safety Champions to ensure appropriate categories are chosen.

2.7 Radiation

South Mimms continues to be compliant for both open source and sealed source ionising radiation work under the Ionising Radiation Regulations (IRR) 2017 and Environment Agency (EA) Environmental Permitting Regulations (EPR) permit EPR/TB3730DV, including the training necessary for non-IR staff. One group has ceased working with open-source IR. The EA EPR permit was updated this year to reflect the changes to the organisation from transformation. There have been incidents reported this year related to changes in staffing and ownership of materials. We have received recommendations following an audit by the external Radiation Protection Advisor (RPA) and work is taking place with the Agency Radiation Protection Officer (RPO) to make improvements to systems and processes and delivery of training.

2.8 Laser Safety

South Mimms and the wider Agency continues to be compliant for its work using lasers and laser products under the Artificial Optical Radiation regulation (2010) regulations made under the Health and Safety at work etc Act, 1974. The staff member who undertook the role of Laser Safety Officer left the Agency following Transformation and we are managing the change through the mapping of safety critical roles to identify a replacement.

2.9 ISO45001 certification

In August 2022, the decision was made to stop the Agency's formal certification to ISO 45001 after it was decided to establish a One Agency system. It was previously only applicable to the lower risk activities at the Canary Wharf site. The intention going forward is to maintain H&S management standards in line with the HSE's Managing for Health and Safety (HSG 65) program, which is the standard already embedded at South Mimms site.

2.10 Fire Risk Assessments and Fire Drills

Actions related to Fire Risk Assessments at both sites have progressed well. Further work will be undertaken in 2022-23 to ensure that the Agency meets its legal duties under the Regulatory Reform Fire Safety Order 2005. Fire drills were undertaken at both sites and lessons learnt communicated.

2.11 Arrangements for Overseas working

Overseas travel resumed at slightly lower levels compared to the pre-COVID-19 levels. The UK and Overseas Working Group continued to meet quarterly. Policies and procedures related to overseas travel have been reviewed and updated, and additional work has been undertaken by the H&S team for staff travelling overseas to ensure travel information and in-country requirements are clear during a spell of coming out of Covid-19 measures and general worldwide instability.

2.12 Occupational Health

The Occupational Health (OH) contract – monthly meetings are held between Human Resources, H&S and the contracted OH provider so that any queries over service delivery or performance reporting can be addressed in a timely manner. A good relationship is being maintained with the service provider.

Diversity and wellbeing/mental health - the diversity and engagement team have created an Agency-wide diversity and mental health monthly campaign with blogs and events on a different theme each month. A regular monthly newsletter has also been launched highlighting what is going on in the Agency,

Additional mental health first aiders were recruited and trained in 2022; there were 24 trained mental health first aiders as March 2023 and names have been posted on INsite and staff noticeboards. Agency staff have access to 'Access at Work Mental Health' which is free for all staff and can be used without the need for referral.

2.13 Policy updates

H&S policies prioritised for review in this financial year have all been updated and published on INsite. Additional reviews have been carried out in response to HSE recommendations and further reviews are required to update documentation to reflect the new organisational structure.

2.14 Key Performance Indicators

a. Risk assessments and COSHH assessments at South Mimms

The KPI for low and medium risk assessments for South Mimms activities fell below the target of 90% and 80% in date at Q3 due mostly to the significant staff changes across the Agency and the need for, risk assessments to be reassigned within the new structure. The H&S Team has made all required changes to the organisational structure within the Safety Organiser system and has moved risk assessments, linked to assessors. Work is being undertaken with risk assessors and risk authorisers to move assessments to the correct Functions and Teams and reassign orphaned risk assessments where assessors have left the organisation. There are no high-level risk assessments out of review period, and COSHH assessments were 90% within review date at Q3, above the 80% target.
The H&S Team will be delivering workshops to support assessors and to improve the quality of risk assessments.

A review will take place in Q1 of the 2023/24 H&S action plan to ensure that improvements are seen in risk assessment review targets.

b. Training statistics and CSL issues

The Agency has been unable to obtain accurate completion data from Civil Service Learning due to staff profiles not being up to date. HR provide regular reminders for mandatory training to be completed.

c. In-person H&S Training

The H&S Team has continued to deliver a significant number of training modules over the past year. All training courses are now delivered through a hybrid method where possible, except where there are practical elements required. This flexibility allows more people to attend and is allowing recovery from a backlog of training. The H&S team has delivered all planned training courses and has delivered additional courses to support the changes in roles following Transformation.

d. Cardinus (Display Screen Equipment (DSE))

Completion rates have remained below target over this year. Changes will be made in the system to reflect the new organisational structure and training will be provided to new DSE assessors to support staff in completing their workstation assessments. The new homeworker module was introduced to support the new hybrid working model.

2.15 Review of internal audit arrangements for all Divisions:

South Mimms – the H&S Team has focused all auditing on high containment activities to ensure legal compliance in these high-risk areas. General H&S management system audits have been put on hold and are now being planned in for Q1 23/24 to work with the new H&S Champion volunteers who are almost all in place.

10SC – Internal divisional safety audits have been put on hold until H&S Champions are in place for all operating groups; question sets will also need to be reviewed in light of the move away from ISO45001. Audits from the new 2023/24 year will focus on high-risk areas in the first instance.

3.0 Future Priorities

The H&S team will continue to support the Agency through the delivery phase of transformation by ensuring we have the appropriate policies, systems and training in place. It will also continue to monitor and review H&S risks and proposes to report on specific areas of interest to senior leaders through the new governance process.

Medicines & Healthcare products Regulatory Agency

BOARD MEETING HELD IN PUBLIC

21 March 2023

Title	**How effective are the Assurance Committees and how can the Terms of Reference for the Board, Executive Committee and Assurance Committees be improved?**
Board Sponsor	Carly McGurry
Purpose of Paper	Approval

How effective are the Assurance Committees and how can the Terms of Reference for the Board, Executive Committee and Assurance Committees be improved?

1. Executive Summary

1.1 This paper details updates to the Board Terms of Reference (ToR) following annual review. It also sets out the conclusions of a recent survey of members on the effectiveness of the Board assurance committees and actions and updated ToR for each committee in response to those conclusions. The Board is asked to approve or provide any comments on the ToR for Board and each committee.

2. Introduction

2.1 The MHRA Board has a standing commitment to review its terms of reference on at least an annual basis, and those of its assurance committees. This paper summarises the main suggested changes and updates to the TOR and sets out the results of a recent survey to assess the effectiveness to date of the assurance committees.

3. Board Terms of Reference

3.1 The governance of the MHRA operates in line with the second model for executive agencies set out in Cabinet Office guidance, with an advisory Board and accountability for successful operation of the Agency held in the Chief Executive and Accounting Officer role. Our arrangements are therefore more complex than a typical organisation and we need a developed understanding of the role of the Board and the Executive and how those best compliment each other. The maturity of our governance structures and relationships continue to grow and ongoing review of ToR is an important checkpoint within that ongoing development.

3.2 Review of the Board's ToR have not identified any major issues of concern and changes proposed are intended to continue to support clear understanding of the respective roles of the Board and the Executive Committee. We have therefore:

- set out, earlier in the document at paragraph 2.1, that the role of the Board is to support the Chief Executive
- changed the language in 3.2 and 13.1 regarding the scheme of delegation to better reflect that the Board, as an advisory board, delegates only to its assurance committees. However, within its responsibilities as drawn from the Framework Agreement and set out in full in 3.2, members will agree which matters should be considered at Board and these will be set out in the Schedule of Reserved Matters attached to the ToR
- brought the provisions on managing conflicts, as set out in full in the Agency's conflict of interest policy, into a separate section so that it is clear to all members and other interested parties the importance of application of this policy and its interaction with the ToR

3.3 The proposed TOR are attached at Annex A. The approved and adopted ToR for the Executive Committee are attached at Annex B, in order that the Board can see how the two forums work together. Next steps for the Executive Committee ToR will be to add to the Reserved Matters Schedule the detail of authority delegated to each of the management committees within the Agency.

4. Effectiveness of Board Assurance Committees

4.1 In December and January, the Governance Office conducted a light-touch review of the Board's assurance committees. This sought feedback from all members of the Board on three questions regarding the committees' success in strengthening assurance to date, how effectively the committees have worked together, and how they might continue to improve and provide further assurance to the Board. All responses were anonymised, and this paper contains an analysis of the responses received.

4.2 This is the first time that we have begun to scrutinise the effectiveness of all three assurance committees, individually and in concert. While there is and will likely always be scope to continue to improve their operation, it is important to record the benefit the committees have provided so far in increasing the Board's capacity to consider and advise on a wider range of work across the Agency. This has been particularly true in response to the Agency's most critical challenges recently – such as in responding to and ensuring we deliver against the recommendations of the Independent Medicine and Medical Devices Safety Review, which the Patient Safety and Engagement Committee (PSEC) has prioritised and helped to navigate effectively. The role of the Organisational Development and Remuneration Committee (ODRC) in supporting the transformation of the Agency has been a considerable amount of work and brought substantial benefit to ensuring clarity of delivery and outcome throughout. The Audit and Risk Assurance Committee (ARAC) has been instrumental in helping the Agency to address the question of financial sustainability, as well as providing constructive challenge across a range of our essential functions, such as risk and internal audit.

4.3 In addition to the survey across all Board members, the Chair of ODRC has met with chief officers to gather detailed feedback and input into the forward programme for ORDC over the year. As per usual practice and best practice requirements, ARAC will also undergo a further and more detailed assessment of its effectiveness prior to the publication of the Agency's annual report. The outcomes of that assessment will be shared with the Board through the Chair of ARAC's assurance report.

5. Survey responses and analysis

5.1 Eight responses were received of the 16 sent out. All responses have been anonymised. The below details the responses to each of the quantitative questions and summarises the additional thoughts provided.

How successful do Board members believe the Assurance Committees are in providing assurance to the full Board?

	Very successful	Successful	Fairly successful	Unsuccessful
ARAC	2	5	1	
ODRC	1	4	3	
PSEC	1	7		

There is a slight variance in responses across the committees, with ODRC receiving a higher proportion of those in the "fairly successful" category. Additional qualitative responses included:

- A view that substantive assurance has not been received in relation to the implementation of One Agency and progress with the Transformation Programme
- The importance of robust data and the quality of information provided to committees to enable them to be effective in providing assurance to the Board.
- A view that ARAC had been established the longest and therefore had more established ways of working, while PSEC is a newer committee and area of focus for the Agency and therefore still developing.

How successful do Board members believe the Assurance Committees have been in working jointly on cross-cutting issues?

There was less variance on whether the committees worked effectively when joining together to work on cross-cutting issues.

	Very successful	Successful	Fairly successful	Unsuccessful
ARAC	1	6	1	
ODRC	1	6	1	
PSEC	1	6	1	

There were slightly differing visions for how joint committees could be used in the future:

- Although the committees have been successful in doing this, it could be used more, particularly to gain assurance on cultural and transformation issues.
- Joint assurance committees should be used selectively to maintain clear areas of responsibility between each of the committees.

How could committees provide additional assurance to the Board?

Responses provided a range of perspectives on how to improve the assurance that committees could provide to the Board. Some of recurring themes concerned ensuring better data and quality of papers for committees, receiving them in a more-timely manner so NEDs had time to digest and critically think about the contents, and a more systematic approach to agenda setting. The individual comments received included:

- Revise and renew the Committees' terms of references
- Schedule deep dives on specific areas of the Delivery Plan
- Focus on risk from different perspectives, systemic enablers of good performance and in particular skills and capability as factors impacting longer term resilience
- Make better use of NED experiences through provision of specific advice and activity/approach NEDs would expect to see in place in the Agency

- Holding committee meetings at different sites to enable engagement with 'front-line' staff and involving employees in discussions, alongside Executives, for an additional, front-line perspective
- Providing some analysis of performance of the Agency as against other ALBs
- Focusing on areas that are not included in the audit programme

5.2 Based on the above, and following discussion with each of the chairs of the committees, we have taken or are proposing the following actions:

a. The ToR for each committee have been brought into the Agency template to ensure consistency with the Board and across the committees where appropriate, and are attached at Annex C
b. The responsibilities of the ODRC have been updated to include specific reference to ongoing change of the Agency and its service redevelopment. This has been drafted broadly to allow the committee scope to add value as appropriate in future.
c. With ongoing development of the Board forward schedule, we are developing a more visible forward schedule for each of the assurance committees, to simultaneously make best use of the time of committees and avoid issues being considered shortly before, after or along a similar line as consideration by the Board. We are also considering the benefit of deep dives and or joint meetings of committees, as well as the need to consider specific elements of the Corporate Risk Register and the upcoming Corporate Plan. We will also explore the possibility of holding meetings of the committees at different sites. As each of the committees complete their work plan for the next twelve months, we will add it to the Board schedule so that all members of the Board have visibility of upcoming discussions.
d. Utilising the forward schedule, Governance Office will continue to engage with Executive colleagues and staff across the Agency to support the development of timely and high-quality papers. In developing the forward schedule, we will look to be as specific as possible on the aim of each agenda item to enable clear commissioning and will develop light-touch guidance with the members of the committees on what good looks like. This will align with a range of work that Governance Office will be taking forward to support staff more broadly on embedding the 'soft' aspects of effective governance.

6. Recommendation

6.1 The Board is asked for approval of or any comments on the updated ToR for the Board and for each committee. The Board is also asked for any comments or guidance on our current and proposed actions to continue to improve the effectiveness of the Board assurance committees.

Carly McGurry
March 2023

Agency Board

Terms of Reference

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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, 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, supported by 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;
- Approves the Agency's Corporate Plan, Business Plan and shorter-term Delivery Plans, which are designed to support achievement of the Agency's strategic objectives, and monitors performance against them;

[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

- 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; and
- Monitors and reviews its own effectiveness on at least an annual basis.

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 Chair and the Chief Executive Officer. The 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.

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 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 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.

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 Chair should determine an appropriate course of action, ranging from exclusion for a particular item of business to cessation of membership. Where the 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, five of whom should be Non-Executive Directors and five of whom should be Executive Directors, plus a 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
- Patient Safety and Engagement Committee
- Organisational Development and Remuneration Committee

9. Frequency of Meetings

9.1. The Board will meet a minimum of nine times per year but may meet more often if required.

10. Format of Meetings

10.1. Board Meetings will be held in Public where 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 Chair will provide an opportunity for members of the public to ask questions directly to the Board 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 in private.

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 MHRA Director of Governance, 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 Board Secretary from the Agency's Governance Office 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:

- Preparing the agenda in consultation with the Chair;
- Developing and maintaining an effective twelve-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 Executive Committee and 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 strategic plan.	Preparation of the Agency's strategic plan for consideration and approval by the Board, ensuring early consultation with the Board.
Consideration and approval of formal strategic partnerships with other organisations.	Recommendations to the Board for formal strategic partnerships with other organisations.
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	Drawing up the annual report for adoption.

Accounting Officer, and following a recommendation from ARAC.	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 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 provided to the Board on the delivery of the agreed plans.

Agency's strategy and its statutory responsibilities.	
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 Agency's organisational structure and People Strategy.	Preparation of the People Strategy and associated policies in consultation with the People and Culture Committee and through the Executive Committee.
The Organisational Development and Remuneration 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.

Executive Committee Terms of Reference

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1. Introduction

1.1. These Terms of Reference set out the principles that should underpin the roles and responsibilities of the Executive Committee and its members. They should be consistent with the Framework Agreement with DHSC, the Agency Board Terms of Reference, the principles of Managing Public Money and the governance framework of the Agency as set out in the Governance Handbook.

2. Purpose of the Executive Committee

2.1. The Executive Committee is responsible for the day-to-day effective leadership and management of the Agency, in support of the Chief Executive. This includes ensuring optimal use of resources, structures and controls to achieve Agency objectives, as well as responsibility for operational and regulatory decisions.

2.2. The Executive Committee supports the Chief Executive in the operational and executive leadership of the Agency through working effectively with the Board to develop strategic and corporate plans to deliver the Agency's objectives and enable performance monitoring against targets. It seeks to take decisions at the right time, based on the right information, to enable the Agency to successfully deliver and to manage risks to our performance. The Committee relies on quality advice from officials and effective decision making throughout the organisation to be effective.

2.3. The Executive Committee operates on a consensus basis. Where consensus cannot be achieved, final decisions (and the responsibility and accountability for those) rest with the Chief Executive as the Accounting Officer of the Agency.

3. Responsibility

3.1. The responsibilities and matters reserved for the Executive Committee are set out in full in the scheme of delegation annexed to these Terms of Reference. However, as the senior Executive forum in the Agency, the Committee will focus on but is not limited to:

- Developing the three-year corporate plan, setting out the strategic focus for the Agency in the next period in an annual business plan, and submitting its plans for review and agreement by the Board
- Delivering the objectives set out in the business plan through delegation of specific responsibilities, optimal use of staff and financial resources and active business management
- Agreeing and overseeing the implementation of the key enabling strategies that cascade from the three-year corporate plan, including but not limited to finance, workforce planning, communications, information technology and operational delivery
- Monitoring and reporting to the Board on the performance against the three-year corporate plan, annual plan and enabling strategies derived from it, taking swift and effective corrective action to address poor performance where needed

- Public health and regulatory decisions, particularly where decisions before the Agency are novel, complex, and, or could have significant strategic, public health or reputational impact
- Management of the Agency's finances, including delivery and maintenance of a clear sustainability strategy and an effective fees framework.

3.2. The Committee will take all significant operational and regulatory policy decisions, such as on proposed changes to the legislative framework or development of new services. The Committee will provide approval of consultations and major publications prior to publishing.

3.3. The Committee will be responsible for ensuring that the Agency establishes and maintains good governance, including:

- A Governance Framework which creates appropriate structures and controls
- 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

3.4. The Committee will engender effective relationships with partner organisations, including agreeing appropriate governance for formal partnerships, and maintaining good communications with the public, industry and the life sciences sector.

3.5. The Committee retains responsibility for the Agency's health and safety responsibilities, in addition to the individual members' responsibilities, as per health and safety legislation. They will be advised in their responsibilities in this regard by both the site-specific Health and Safety Groups, which can, by exception, escalate issues directly to the Executive Committee where a risk of major harm is identified, and by the Risk and Assurance Group which provides routine oversight of health and safety responsibilities, including mental health and wellbeing.

3.6. The Committee will review and agree all Board Papers prior to their submission to the Board.

4. Standing items

4.1 The Executive Committee will consider a number of standing matters each month, including:

- Financial performance, informed by the advice of the Resources Committee
- Agency performance, informed by the advice of the Delivery and Performance Committee
- Agency Board agenda and papers
- Routine reporting from all sub-committees
- Assessment of legal risk

4.2 On a quarterly basis, the Executive Committee will consider performance against the Agency delivery plan. It will also consider the key strategic risks facing the Agency on a quarterly basis. On an annual basis, the Committee will review the Terms of Reference and the Health and Safety annual plan.

5. Composition

5.1. The Committee will be formed of the Chief Executive and Executive Directors, who are responsible for the effective management of their Groups. The Committee is chaired by the Chief Executive, who may nominate an alternative chair in their absence.

5.2. Executive Directors will include:

- Chief Science, Research and Innovation Officer
- Chief Healthcare, Quality and Access Officer
- Chief Safety Officer
- Chief Partnerships Officer
- Chief Finance Officer
- Chief Technology Officer

6. Membership

6.1. The Committee is supported by directors of key enabling and corporate services. They will attend all Executive Committee meetings as advisory members to contribute to discussions, although formal decision-making responsibility remains with the Chief Executive and Executive Directors. Advisory members include:

- Director of Communications
- Director of Human Resources
- Director of Delivery
- Director of Governance

6.2. If a member is unavailable, a deputy can attend in their place with the prior notification of the Chair.

7. Conflicts

7.1. If during the meeting a potential conflict of interest arises with matters under consideration, the member or advisory member concerned must declare it and withdraw from the meeting, or part of the meeting, as appropriate and in accordance with the staff conflicts of interest policy. This will be recorded in the minutes.

8. Quorum

8.1. A quorum for meetings will consist of four members and must include the Chief Executive or Chief Finance Officer. Where either the Chief Executive or Chief Finance Officer has nominated a deputy to chair or attend the meeting in their absence, those deputies are empowered to take decisions and will be accounted for in the quorum.

8.2. If a member of the Committee 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.

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

9. Sub-committees

9.1. The Executive Committee will devolve certain areas of its business to sub-groups. The Committee may also initiate time-limited programmes of work, each led by a designated member of staff. The sub-committees include:

- Risk and Audit Group
- Digital, Data and Technology Committee
- Resources Committee
- People and Culture Committee
- Delivery and Performance Committee
- Strategic Change Committee

9.2. Each sub-committee will have a formal Terms of Reference which must be agreed by the Executive Committee. Each sub-committee will complete routine reporting into the Executive Committee to enable easy communication and clear visibility of emerging issues and decisions. Each sub-committee will be able to escalate decisions to the Executive Committee which exceed their authority or require discussion and decision by all members of the Executive Committee.

10. Frequency of Meetings

10.1. The formal responsibilities of the Committee will be carried out through two monthly meetings. Extraordinary meetings to discharge formal business can be arranged as necessary.

10.2. The Committee will meet weekly to discharge decisions related to the Agency's redesign of its services. The Committee will formally agree when these meetings are no longer required as the implementation of the service redesign becomes embedded into the new operating model of the Agency.

10.3. The Committee may meet informally to share intelligence on emerging issues, to highlight key events ahead or to discuss other concerns at the direction of the Chair.

11. Attendance

11.1. Other individuals may be invited to attend for all or part of any meeting for a specific agenda item, however, their attendance will be limited to this item only.

12. Secretariat

12.1. The Committee Secretariat will be responsible for:

- Preparing the agenda in consultation with the Chair
- Circulating Committee papers to members and invitees, normally two working days before each meeting
- Work with officials to ensure quality criteria are met for Executive Committee papers, with the authority of the Committee to refuse any papers which do not meet the required standard or are submitted late

- Producing and circulating draft minutes of the Committee meetings to members, normally within three working days after the meeting
- Maintaining an action log
- Ensuring timely publication of papers and minutes to support transparency in the operations of the Committee, other than where the Committee has agreed such papers or minutes contain confidential information.

12.2. Chief Officers are responsible for providing information to the Secretariat on matters that will need to be considered by the Executive Committee in good time to enable effective planning of the forward agenda.

13. Delegation of Authority

13.1. The Executive Committee must operate within the limits of the Agency's statutory authority and within the limits set out in the Framework Document. However, the Committee may delegate authority to its management committees and other bodies in line with its own limits of authority. These delegations will be recorded in the terms of reference for those bodies and reflected in the schedule of reserved matters below.

13.2. The Committee can investigate or have investigated any activity in-line with its responsibilities, as set out in these Terms of Reference. In doing so, the Committee can rightfully inspect any relevant documents, ensuring that data, confidentiality and security are maintained, and all relevant policies adhered to. It may seek relevant information from any employee, committee, sub-committee or group to assist it in the delivery of its functions.

14. Review of Terms of Reference

14.1. These terms of reference will be reviewed by the Board and agreed annually by the Executive Committee.

15. Annex A: Schedule of reserved matters

Certain matters are reserved for the Executive Committee and cannot be decided at either a sub-committee or within the authority of a business unit (referred to as Groups). These matters are as follows:

- Development and approval of the Agency's corporate and business plans, with consideration and advice from the Agency Board
- Approval of the Agency's operational budget each financial year, in advance of submission to the Board, and approval of proposals relating to significant underspends or redesignations of budget in year which exceed the delegated authority of the Resources Committee and or put the achievement of a strategic commitment in the Corporate or Business Plan at substantial risk
- Decisions on key matters of public health that are novel, contentious, or high-profile emerging issues, address UK wide priorities or alter the Corporate or Business Plans.
- Approval of proposals for redesign of Agency services and procedures that substantially alter existing custom and practice or the balance of risk in fulfilling our statutory regulatory activities
- Strategic initiatives which arise outside of the regular corporate and business plan cycle which would involve a change to our strategic objectives, a change to the organisational structure that invokes the Agency's Change Management policy and or exceeds the budgetary delegation of the Resources Committee.
- Management and approval of the Agency's corporate risk register, as advised by the Risk and Audit Group
- Approval of substantial contracts which bind the Agency to long or costly commitments, or which are novel or contentious and of any major investments which expose the Agency to considerable risk
- Approval of partnership agreements with other organisations
- Approval of the external and internal elements of the governance framework in partnership with the Board
- Approval of prominent or contentious publications, consultations, policy decisions and legislative frameworks
- Development of the fees strategy, specific fee changes at a strategic level and the framework for future operation
- Approval of the Agency annual report and accounts, ahead of submission to the Board and recommendation for signature by the Chief Executive
- Internal Audit plan, ahead of submission to the Audit and Risk Assurance Committee
- Health and safety annual plan for approval and health and Safety compliance at Agency level, including immediate review of any major health and safety incidents or near misses
- Development of Spending Review bids and leadership of negotiations with DHSC and HMT as needed to support successful settlement
- Approval of pay policy and employment frameworks, as advised by the People and Culture Committee, including the pay remit and reward strategy

- Development of the accommodation strategy, including current contracts and future approach to location
- Development of the people strategy and policy with identified agency-wide implications, as advised by the People & Culture Committee, including engagement and diversity & inclusion

Audit and Risk Assurance Committee

Terms of Reference

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1. Introduction

1.1. These Terms of Reference set out the principles that should underpin the roles and responsibilities of the Audit and Risk Assurance Committee, as a committee of the MHRA Board. These Terms of Reference should be consistent with the roles and responsibilities set out in the MHRA Board Terms of Reference, which are themselves consistent with wider applicable guidance and requirements.

2. Purpose of the Audit and Risk Assurance Committee

2.1. The purpose of the Audit and Risk Assurance Committee (ARAC) is to support the MHRA Board and the Chief Executive as Accounting Officer in their responsibilities for management of risk, control and governance.

2.2. The Committee reviews the comprehensiveness of assurances in meeting the Board and Accounting Officer's assurance needs. The Committee reviews and advises upon the reliability and integrity of these assurances.

3. Responsibility

3.1. The Committee operates in an independent advisory capacity, providing advice to the Board and Accounting Officer on:

- Assurances relating to the effectiveness of processes for identification and management of risk, the operation of controls and governance, the governance statement and achievement of value for money.
- 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.
- Adequacy of management response to issues identified by audit activity, including external audit's management letter.
- Anti-fraud policies, whistle-blowing processes, management of conflicts of interest and arrangements for special investigations.
- Its own effectiveness, which the Committee will review periodically and report the results of that review to the Board.

3.2. To fulfil these responsibilities, for each meeting ARAC will be provided with:

- A report summarising any significant changes to the organisation's strategic risks and a copy of the Corporate Risk Register.
- A progress report from the Head of Internal Audit summarising work performed against plan, key issues emerging, management responses and any resourcing issues affecting the delivery of the objectives of internal audit
- A progress report (written or verbal) from the External Audit representative

summarising work done and emerging findings.

3.3. As and when appropriate the Committee will also be provided with:

- Proposals for the terms of reference of internal audit/the internal audit charter
- The internal audit strategy.
- The Head of Internal Audit's Annual Opinion and Report.
- Quality Assurance reports on the internal audit function.
- The draft accounts of the organisation.
- The draft Governance Statement.
- A report on any changes to accounting policies.
- External Audit's management letter.
- A report on co-operation between internal and external audit.
- The organisation's Risk Management strategy.
- Management assurance reports focused on specific risks and issues e.g., health and safety detailing the challenges/ mitigations and controls of our live risks and issues

3.4 The ARAC holds no decision-making power, nor does it exercise any line management or executive functions. It may suggest and agree actions with the Executive and may make recommendations to the Board, who retain decision-making responsibility in respect of the functions set out in its Terms of Reference. This does not prevent the ARAC from fulfilling its responsibilities to report to the Board and offer its view on the assurance provided as detailed in paragraph 13.

4. Composition

4.1 Membership of the ARAC, appointed by the Board, will consist of three non-executive members of the Board, one of whom will be appointed as Chair. Any of the non-executive members can deputise in the Chair's absence.

4.2 Members should together possess the appropriate range of skills in risk, governance and internal control, including recent and relevant financial experience.

4.3 All new members will be provided with induction training and the MHRA will provide for any additional development which is deemed necessary for the member to fulfil their role on the Committee. The Chair of the Audit and Risk Assurance Committee will hold an annual review with each member and any training or development needs will be taken forward with the agreement of the Chair and Accounting Officer.

5. Membership

5.1. Committee meetings will normally also be attended by the Chief Executive Officer as Accounting Officer, the Chief Finance Officer, Director of Governance, Head of Internal Audit, and a representative of External Audit. The Head of Internal Audit and the representative of External Audit will have free and confidential access to the Chair of the

Audit and Risk Assurance Committee.

5.2. The Committee 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.

5.3. Where unavoidable, deputies for executive members should be agreed in advance with the Chair. Once admitted, deputies have the same rights and responsibilities within ARAC as non-deputies.

6. Conflicts

6.1. 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.

7. Quorum

7.1. A quorum for meetings will consist of a minimum of two of the three non-executive members.

7.2. If a meeting is not quorate it may still proceed, with agreement from a majority of Committee members (including those not in attendance). In such circumstances, any proposed recommendations to the Board will be non-binding and will require subsequent ratification from a quorate meeting or with absent members by correspondence.

8. Sub Committees

8.1. The Committee may, subject to the approval of the Board, establish sub-committees to carry out specific aspects of Committee business, on its behalf.

9. Frequency of Meetings

9.1. The Committee will meet quarterly and at least four times a year. Additional meetings may be called at the discretion of the Chair.

9.2. The Board or the Chief Executive may ask the Committee to convene further meetings to discuss particular issues on which they want the Committee's advice.

9.3. The Committee will hold closed meetings at least annually with Internal Audit and the National Audit Office.

10. Attendance

10.1. Other individuals may be invited to attend for all or part of any meeting for a specific agenda item.

11. Secretariat

11.1. The ARAC will be supported by a Committee Secretary from within the Agency's Governance Office. The Secretary will be responsible for:

- Preparing the agenda in consultation with the Chair
- Developing and maintaining a twelve-month schedule for the ARAC which aligns with the Board schedule and ARAC's responsibilities, avoiding duplication and enabling timely consideration of key matters
- Commissioning Committee papers with clear deadlines, sufficient notice and working with staff to continually improve the quality of papers
- Circulating Committee papers to members and invitees a minimum of five working days before each meeting
- Producing and circulating draft minutes of the Committee meetings to members, within ten working days after each meeting
- Maintaining an action log

12. Delegated Authority

12.1. The Board authorises ARAC to investigate or have investigated any activity in line with its responsibilities, as set out in these Terms of Reference. In doing so, the Committee can rightfully inspect any documents, ensuring that data, confidentiality and security are maintained, and all relevant policies adhered to. It may seek relevant information from any employee, other committee, sub-committee or Group set up by the Board to assist it in the delivery of its functions.

13. Reporting to the Board

13.1. Following each Committee meeting, and at the next appropriate meeting of the Board, ARAC will formally report to the Board on the assurance it can provide on the matters set out in paragraph 3.1. This written assurance report will be agreed by the non-executive members of ARAC. The Chair will use the assurance report to draw to the attention of the Board any issues that require disclosure to the full Board, or that, in the view of ARAC, require executive action.

14. Review of these Terms of Reference

14.1. The Committee will review its Terms of Reference at least annually. Amendments will be subject to review and approval by the Agency Board.

Patient Safety and Engagement Committee

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14. Review of these Terms of Reference 6

1. Introduction

1.1. These Terms of Reference set out the principles that should underpin the roles and responsibilities of the Patient Safety and Engagement Committee, as a committee of the MHRA Board. These Terms of Reference should be consistent with the roles and responsibilities set out in the MHRA Board Terms of Reference, which are themselves consistent with wider applicable guidance and requirements.

2. Purpose of the Patient Safety and Engagement Committee

2.1. The purpose of the Patient Safety and Engagement Committee (PSEC) is to provide independent and objective advice, assurance and recommendations to the MHRA Board and Chief Executive on their responsibilities relating to patient safety and patient engagement, such that these are paramount in decision-making throughout the MHRA.

3. Responsibility

3.1. It is the responsibility of the PSEC to:

- Examine, scrutinise and challenge the management and operation of increased patient engagement, to deliver outcomes in line with the accepted recommendations of the Independent Medicines and Medical Devices Safety Review
- Provide challenge to the Executive on the delivery of the Agency's statutory duties in a way that is responsive to the needs of patients and their concepts of risks and benefits and in its consideration of patient safety
- Consider and advise on the extent to which processes are in place to encourage the acquisition, analysis and decision-making based on information from patients and the public at all stages of the Agency's regulation of medicines, medical devices and blood products
- Scrutinise the systems in place to ensure information is shared effectively with patients and the public on the outcome of their involvement in Agency decisions, and on wider activities and operations of the Agency

3.2. To meet these responsibilities, PSEC will:

- Scrutinise the processes, systems and structures within the Agency to ensure that patient and public engagement is utilised throughout regulation, including the initial assessment of medicines, medical devices and blood products, surveillance of their use and decisions made as a result of possible safety signals.
- Seek assurance that the Agency has appropriate procedures in place for preventing, detecting and addressing any safety or quality issues with medicines, medical devices or blood products in the interests of patient safety
- Seek assurance that the patient/public perception and concepts of risk and benefit can be incorporated into regulatory decision-making
- Provide guidance and input into the development of strategies which seek to maximise Agency engagement with patients and the public

- Provide constructive challenge to the Executive on regulatory systems and processes that could be modified to further improve patient safety and patient engagement

3.3. The PSEC holds no decision-making power, nor does it exercise any line management or executive functions. It may suggest and agree actions with Executive members and may make recommendations to the Board, who retain decision-making responsibility in respect of the functions set out in its Terms of Reference. This does not prevent PSEC from fulfilling its responsibilities to report to the Board and offer its view on the assurance provided as detailed in paragraph 13.

4. Composition

4.1. Membership of PSEC, appointed by the Board, will comprise a minimum of three non-executive members, one of who will be appointed as Chair and three executive members, including the Chief Executive Officer. Any of the non-executive members can deputise in the Chair's absence.

4.2. In addition to the Chief Executive Officer, the Chief Safety Officer and the Chief Healthcare Quality and Access Officer will serve as members of the PSEC.

4.3. PSEC will also appoint two independent lay members who will hold non-voting positions on the Committee, to supplement its range of skills and experience and embed a robust lay perspective in discussions.

5. Membership

5.1. Committee meetings will also be regularly attended by other members of the Executive, such as the Chief Officer for Science, Research and Innovation and the Chief Partnerships Officer as the agenda demands. The Director of Delivery and the Chief Digital and Technology Officer will also be invited as required.

5.2. The Committee 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.

5.3. Where unavoidable, deputies for executive members should be agreed in advance with the Chair. Once admitted, deputies will have the same rights and responsibilities within PSEC as non-deputies.

6. Conflicts

6.1. 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.

7. Quorum

7.1. A quorum for meetings will consist of five members, including at least two non-executive members, at least two executive members and at least one lay member.

7.2. If a meeting is not quorate it may still proceed, with agreement from a majority of Committee members (including those not in attendance). In such circumstances, any proposed recommendations to the Board will be non-binding and will require subsequent ratification from a quorate meeting or with absent members by correspondence.

8. Sub Committees

8.1. The Committee may, subject to the approval of the Board, establish sub-committees to carry out specific aspects of Committee business, on its behalf.

9. Frequency of Meetings

9.1. The Committee will meet quarterly, taking account of the Board's schedule of business. Additional meetings may be called, or meetings postponed as necessary.

9.2. The Board or Chief Executive may ask the Committee to convene further meetings to discuss particular issues on which they want the Committee's advice.

10. Attendance

10.1. Other individuals may be invited to attend for all or part of any meeting for a specific agenda item.

11. Secretariat

11.1. The PSEC will be supported by a Committee Secretary from within the Agency's Governance Office. The Secretary will be responsible for:

- Preparing the agenda in consultation with the Chair
- Developing and maintaining a twelve-month schedule for the PSEC which aligns with the Agency Board schedule, avoiding duplication and enabling timely consideration of key matters
- Commissioning Committee papers with clear deadlines, sufficient notice and working with staff to continually improve the quality of papers
- Circulating Committee papers to members and invitees a minimum of five working days before each meeting
- Producing and circulating draft minutes of the Committee meetings to members, within ten working days after each meeting
- Maintaining an action log

12. Delegated Authority

12.1. The Board authorises the PSEC to investigate or have investigated any activity in line with its responsibilities, as set out in these Terms of Reference. In doing so, the Committee can rightfully inspect any documents, ensuring that data, confidentiality and

security are maintained, and all relevant policies adhered to. It may seek relevant information from any employee, other committee, sub-committee or Group set up by the Board to assist it in the delivery of its functions.

13. Reporting to the Board

13.1. Following each Committee meeting, and at the next appropriate meeting of the Agency Board, PSEC will formally report to the Board on the assurance it can provide on the matters set out in paragraph 3.1. The Chair will use the assurance report to draw to the attention of the Board any issues that require disclosure to the full Board, or that, in the view of PSEC, require executive action.

14. Review of these Terms of Reference

14.1. The Committee will review its Terms of Reference at least annually. Amendments will be subject to review and approval by the Agency Board.

Organisational Development and Remuneration Committee

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1. Introduction

1.1. These Terms of Reference set out the principles that should underpin the roles and responsibilities of the Organisational Development and Remuneration Committee, as a committee of the MHRA Board. These Terms of Reference should be consistent with the roles and responsibilities set out in the MHRA Board Terms of Reference, which are themselves consistent with wider applicable guidance and requirements.

2. Purpose of the Organisational Development and Remuneration Committee

2.1. The purpose of the Organisational Development and Remuneration Committee (ODRC) is to provide independent and objective advice, assurance and recommendations to the MHRA Board and the Chief Executive on their responsibilities relating to the development of the organisation and its services to deliver the strategic objectives of the Agency, its people and culture strategies and implementation to support delivery of those strategic objectives and scrutiny of senior reward recommendations.

3. Responsibility

3.1. It is the responsibility of the ODRC to:

- Provide assurance to the Board that the Agency has appropriate culture and procedures in place for managing and developing its workforce capabilities and delivering change
- Examine, scrutinise and challenge the management and delivery of change and transformation in the Agency, in order to provide advice to the Chief Executive and assurance to the Board that the development of the Agency will equip it to adequately meet its strategic objectives
- Scrutinise the processes, systems and structures in place within the Agency to attract, retain, and develop staff capabilities and retain talent in a changing environment
- Provide challenge to the Executive on the development and implementation of the People Strategy
- Provide a formal and transparent process for determining Executive remuneration
- Review its own effectiveness periodically and report the results of that review to the Board

3.2. To fulfil these responsibilities, ODRC will ensure a high standard of beneficial discussion at each meeting. Non-executive members of the ODRC will use their experience and skills to provide constructive, effective and objective challenge to Executive members and provide an independent perspective on the matters listed in 3.1. Executive members of the ODRC will provide expertise and in-depth knowledge of the Agency's operations, opportunities and risks to enable the ODRC to discharge its responsibilities as listed in 3.1.

3.3. The ODRC holds no decision-making power, nor does it exercise any line management or executive functions. It may suggest and agree actions with Executive members and may

make recommendations to the Board, who retain decision-making responsibility in respect of the functions set out in its Terms of Reference. This does not prevent the ODRC from fulfilling its responsibilities to report to the Board and offer its view on the assurance provided as detailed in paragraph 13.

4. Composition

4.1. Membership of ODRC, appointed by the Board, will consist of three non-executive members, one of whom will be appointed as Chair, and three executive members, including the Chief Executive Officer. Any of the non-executive members can deputise in the Chair's absence.

4.2. In addition to the Chief Executive Officer, the Chief People Officer and Chief Digital and Technology Officer will serve as members of the ODRC.

5. Membership

5.1. Committee meetings will also be regularly attended by the Director of Delivery. The Committee 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.

5.2. Where unavoidable, deputies for executive members should be agreed in advance with the Chair. Once admitted, deputies have the same rights and responsibilities within ODRC as non-deputies.

6. Conflicts

6.1. 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.

7. Quorum

7.1. A quorum for meetings will consist of four members, with at least two executive members and at least two non-executive members present.

7.2. If a meeting is not quorate it may still proceed, with agreement from a majority of Committee members (including those not in attendance). In such circumstances, any proposed recommendations to the Board will be non-binding and will require subsequent ratification from a quorate meeting or with absent members by correspondence.

8. Sub Committees

8.1. The Committee may, subject to the approval of the Board, establish sub-committees to carry out specific aspects of Committee business, on its behalf.

9. Frequency of Meetings

9.1. The Committee will meet quarterly, taking account of the Agency's cycle for talent management and remuneration processes. Additional meetings may be called, or meetings postponed as necessary.

9.2. The Board or the Chief Executive may ask the Committee to convene further meetings to discuss particular issues on which they want the Committee's advice.

10. Attendance

10.1. Other individuals may be invited to attend for all or part of any meeting for a specific agenda item.

11. Secretariat

11.1. The ODRC will be supported by a Committee Secretary from within the Agency's Governance Office. The Secretary will be responsible for:

- Preparing the agenda in consultation with the Chair
- Developing and maintaining a twelve-month schedule for the ODRC which aligns with the Board schedule, avoiding duplication and enabling timely consideration of key matters
- Commissioning Committee papers with clear deadlines, sufficient notice and working with staff to continually improve the quality of papers
- Circulating Committee papers to members and invitees a minimum of five working days before each meeting
- Producing and circulating draft minutes of the Committee meetings to members, within ten working days after each meeting
- Maintaining an action log

12. Delegated Authority

12.1. The Board authorises the ODRC to investigate or have investigated any activity in line with its responsibilities, as set out in these Terms of Reference. In doing so, the Committee can rightfully inspect any documents, ensuring that data, confidentiality and security are maintained, and all relevant policies adhered to. It may seek relevant information from any employee, other committee, sub-committee or Group set up by the Board to assist it in the delivery of its functions.

13. Reporting to the Board

13.1. Following each Committee meeting, and at the next appropriate meeting of the Board, ODRC will formally report to the Board on the assurance it can provide on the matters set out in paragraph 3.1. The chair will use the assurance report to draw to the attention

of the Board any issues that require disclosure to the full Board, or that, in the view of ODRC require executive action.

14. Review of these Terms of Reference

14.1. The Committee will review its Terms of Reference at least annually. Amendments will be subject to review and approval by the Agency Board.