Medicines & Healthcare products Regulatory Agency

AGENDA FOR BOARD MEETING HELD IN PUBLIC

10:00 am – 12:30 pm on Tuesday 17 January 2023

Chair: Stephen Lightfoot

	AGENDA ITEM	**PURPOSE**	**PRESENTER**
10:00	INTRODUCTION		
	1. What is the purpose of this meeting, who are the Board Directors 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
10:40	5. What was the financial and people performance of the MHRA for the year up to 30 November 2022?	Assurance	John Taylor
11:00	6. What assurance can be provided by the Audit & Risk Assurance Committee?	Assurance	Paul Goldsmith
	DYNAMIC ORGANISATION		
11:10	7. How will the new MHRA People Strategy improve the recruitment, diversity, development and retention of our staff to deliver our statutory responsibilities?	Assurance	Vanessa Birchall-Scott
11:30	8. What assurance can be provided by the Organisational Development & Remuneration Committee?	Assurance	Mandy Calvert
	PATIENT SAFETY		
11:40	9. What assurance can be provided by the Patient Safety & Engagement Committee?	Assurance	Mercy Jeyasingham

	GOVERNANCE		
11:50	10. How will the Assurance and Governance Framework of the MHRA continue to be improved?	Approval	Carly McGurry
	EXTERNAL PERSPECTIVE		
12:10	11. What questions do members of the public have about the items on this Board Meeting Agenda?	Public Engagement	Chair
12:30	CLOSE OF MEETING		

MHRA Board Declarations of Interest – January 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
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
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
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

Name and MHRA Role	Name of Other Company or Organisation	Nature of interest	Paid	Current
	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	Shareholder	Yes	Yes
	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
	WHO – Sustainable COVAX Manufacturing Strategy for Regional Health Security	Advisory Expert	No	Yes
	UK Health Security Agency	Associate Non-Executive Board Member	Yes	Yes

Name and MHRA Role	Name of Other Company or Organisation	Nature of interest	Paid	Current
Laura Squire OBE Chief Healthcare Quality & Access Officer	None	N/A	N/A	N/A
John Taylor Interim Chief Finance 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 15th November 2022

(10:00 – 12:40)

Large Meeting Room, NIBSC, Blanche Lane, South Mimms

Present:

The Board

Stephen Lightfoot	Chair
Dame June Raine DBE	Chief Executive
Dr Marc Bailey	Chief Science, Research & Innovation Officer
Dr Alison Cave	Chief Safety Officer
Amanda Calvert	Non-Executive Director
Professor Graham Cooke	Non-Executive Director and Deputy Chair (via Zoom)
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
Michael Whitehouse OBE	Non-Executive Director

Others in attendance

Rachel Bosworth	Director of Communications and Engagement, MHRA
Natalie Richards	Head of the Executive Office, MHRA
Kathryn Glover	Deputy Director, Medicines Regulation and Prescribing, DHSC
Puja Myles	Director, Clinical Practice Research Datalink (CPRD)
Phil Tregunno	Deputy Director, Patient Safety Monitoring

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 Junaid Bajwa, Non-Executive Director; John Taylor, Interim Chief Finance Officer; Glenn Wells, Chief Partnerships Officer; Carly McGurry, Director of Governance; 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. Paul Goldsmith informed the Chair of an update – Closed Loop Medicine has now submitted a marketing authorisation. Graham Cooke informed the Chair that his DOIs should be updated due to his involvement in a project between Imperial College Healthcare Partners and Pfizer, his involvement in a successful application for an influenza platform trial in the UK as part of the REMAP CAP study, and his consultant role at Imperial College NHS Trust and Chelsea & Westminster NHS Trust.

The Chair reviewed the new and 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 current 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 the novel oral polio vaccine; the WHO global polio eradication initiative; tuberculosis vaccine discovery work; influencing regulatory and clinical practice; bacterial vaccines; development of an international standard for Rift Valley Fever Virus; a new potency assay for Influenza vaccines; diagnostics for clinical oncology; diagnostics and the microbiome; and the WHO Expert Committee on Biological Standardisation;

(ii) Healthcare Access – including updates on COVID-19 vaccines; a new anti-epileptic medicine, cenobamate; nicotine e-cigarettes; the lenalidomide Pregnancy Prevention Programme; remote inspections; and Software and Artificial Intelligence AI as a Medical Device;

(iii) Patient Safety – including updates on the Yellow Card Scheme; medicines safety issues resulting in regulatory action for methylphenidate, pholcodine, rucaparib and teicoplanin; the Interim Devices Working Group; Manufacturers' on-line reporting of device incidents; and the work of the Criminal Enforcement Unit;

(iv) Partnerships – including updates on regulatory reform; the British Pharmacopoeia; global collaboration on compliance; innovative licensing; and the International Coalition of Medicines Regulatory Authorities (ICMRA);

(vi) Dynamic Organisation – including updates on the Agency data centre move; and control testing activities;

(vii) Financial Sustainability – including an update on the Agency 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 the Cumberlege Review; ensuring greater collaboration with our international peer regulators; considering other regulators roadmaps for software and AI as a Medical Device; progression on recruitment to key roles; the work of the Patient Safety and Engagement Committee; and the Agency's compliance strategy. An action was taken to review the Agency's compliance strategy at the Board. The Board thanked Dr Raine for this report and expressed its thanks and gratitude to all members of staff at the MHRA.

Action 88: Present a review of the Agency's Compliance Strategy to the Board in the new year ***Laura Squire***

Item 5: How much of the MHRA Delivery Plan was delivered and what was the operational performance of the Agency in the second quarter of 2022/23?

5.1 The Board considered a report on Delivery Plan implementation and operational performance of the Agency for the second quarter of 2022/23. The Board noted the report and provided comments relating to ensuring rigor on timelines; ensuring any risks relating to patient safety deliverables are carefully mitigated; utilising the internal patient champions network and patient training; ensuring the people strategy, talent management model and engagement with staff to refresh the vision statement are carefully monitored to bring back on track; progress on the Regulatory Management System (RMS) to deliver a minimum viable product. The Board noted the report on the Delivery Plan with thanks and were pleased with the overall progress.

5.2 The Board considered the report on operational performance of the Agency and provided comments relating to the amount of resource which is used addressing the 5500 queries received via the Customer Experience Centre each month; volumes of clinical trials and clinical investigations approved in the UK per quarter; the 30 new active substance licences which were granted in the second quarter of 2022/23 across 15 therapeutic areas; appointment of staff to roles to address the high volumes of established medicine applications; understanding future needs, supply risks, and other

horizon scanning activities; trends and the scale of COVID-19 vaccine ADR reports; how to present benefit risk evaluation and actions taken to minimise risk in the performance report; patient engagement; NHS implementation; the decrease in staff turnover; and the importance of including analysis which demonstrates value for money in the performance report. An action was taken to include digital and partnership in future reports.

Addition to action 51: 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. John Taylor

SCIENTIFIC INNOVATION

Item 6: How is the MHRA providing safe access to data for research?

6.1 The Board considered a report on how the MHRA is providing safe access to data for research. Puja Myles, Director of the Clinical Practice Research Datalink (CPRD), joined for the discussion. The Board noted that in recent years there has been a growing public awareness of data privacy and calls for greater transparency of data sharing, including assurances that healthcare data is safe, secure, and only used for its intended purposes. This has led to Trusted Research Environments (TRE) being considered the future method for access of healthcare data. TREs differ from more widely used models of data access as researchers can only access and analyse the data within the secure environment.

6.2 CPRD is the MHRA's specialist real world data research service and has provided access to anonymised patient data for research for the benefit of public health for 35 years. CPRD has an excellent track record in ensuring that data is safe, secure, and only used for its intended purposes by following the Five Safes Framework, as recently validated by an external NHS Audit. CPRD's implementation of the Five Safes Framework can be further strengthened and streamlined by the development of the CPRD TRE. This will require a combination of technology, client engagement, and collaboration with UK-wide bodies to ensure policy and strategy strikes a balance between reassuring patients that their data is safe and only used for its intended purpose, whilst ensuring the UK is a global leader in innovative public health research.

6.3 The Board considered the paper and provided comments on working with stakeholders across the health data sector to ensure work is coordinated; ensuring the recommendations in the Goldacre Report are carefully considered, noting the MHRA is working closely with NHS Digital to address any concerns; managing any risks on the transition; how to improve data quality, scope and coverage, and addressing any inadvertent bias in the database. The Board thanked Dr Myles and endorsed the strategy of using a predominantly TRE-based access model for healthcare data; an update should be provided on progress when appropriate.

Item 7: What are the priorities for the MHRA Science Strategy to enable scientific innovation in the UK?

7.1 The Board considered a paper describing the priorities for the MHRA Science Strategy to enable scientific innovation in the UK. The new Agency Science Strategy aims to maintain and grow the MHRA's world leading reputation for scientific excellence by both maintaining the science that is unique to the Agency, partnering with leading scientific experts and nurturing new ideas. The UK is a leader in scientific innovation and the MHRA has a pivotal role in applying its scientific knowledge to ensure that scientific innovation in healthcare products in the UK is safely and effectively transferred into benefits for Patients and Public Health.

7.2 The Board noted that the Strategy must enable the Agency to identify relevant emerging and existing scientific areas that can be applied to improving regulation. The Science Strategy will support the growth and maintenance of the knowledge and expertise required to do this. The Board considered a proposed framework within the Strategy for identifying the science to be done by the Agency in partnership with others and identifying how this science supports the application of healthcare product innovations.

7.3 The Board provided comments on undertaking broad enabling actions which will facilitate research, wider than this strategy; focus on social science and behavioural science; utilising partnerships to drive this work forward; the importance of good data; inequalities; increasing use of alternatives to animal models; development of specific centres of excellence; the Access Consortium; the UK Stem Cell Bank; ensuring the final strategy has clear prioritisation; ensuring the Agency's vaccine and biologicals work is included as a specific area of expertise; and the importance of a review of scientific committees. The Board noted the report with thanks.

Addition to action 29: 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***

PATIENT SAFETY

Item 8: How will the new MHRA SafetyConnect system deliver more responsive safety surveillance?

8.1 The Board considered a report describing progress and next steps with the SafetyConnect programme. Phil Tregunno, Deputy Director Patient Safety Monitoring, joined for the discussion. The Board noted that several enhancements have been delivered to date as assurance of progress towards the vision of a more responsive safety surveillance system for all medical products.

8.2 The Board provided comments relating to how active surveillance will feed into regulation of new medicines on conditional approvals; the wide range of data sources; the ability to collect specific information as it arises; improved engagement capabilities; the patient journey; transparency; the integration between the NHS App and SafetyConnect; GDPR compliance; health economics; analytical capabilities of the platform; and facilitating reporting. The Board thanked all involved in development of SafetyConnect and were assured on the progress of delivery of this system.

DYNAMIC ORGANISATION

Item 9: What assurance can be provided from the Joint Organisational Development & Remuneration Committee and Audit & Risk Assurance Committee?

9.1 The Board considered an assurance report provided by the Joint Organisational Development & Remuneration Committee (ODRC) and Audit & Risk Assurance Committee (ARAC). The joint ODRC and ARAC met on 12th October 2022 with the objectives of reviewing the progress and plans for implementation of the Regulatory Management System (RMS) project; understand how the RMS will enable delivery of key regulatory services; understand the data strategy for RMS; and discuss the risks and dependencies for the project. The Board noted that both committees have assurance responsibilities that are dependent upon the successful implementation of the RMS, and this was an excellent opportunity to review progress together.

9.2 The joint ODRC and ARAC were encouraged by the progress that is being made. There is close collaboration at leadership level and across the different parts of the Agency. The definition of the new services and ways of working did not reach the level of maturity hoped for in the transformation programme but are now being defined in the RMS project discovery process. The importance of designing the processes and systems to meet future needs is understood by the team and the RMS remains a cornerstone for the delivery of the One Agency strategy and business plan. There are strong governance processes in place both within the project team and through the Project Board and Strategic Change Committee processes. The delivery of the Minimum Viable Product will be challenging as there is much to do, but the plans look realistic, and the programme is currently on plan and budget at this stage. Resourcing remains a key risk to the programme and is under constant review. The ARAC and ODRC will continue to seek assurance that the programme is progressing to plan and will report to the Board periodically. The Board thanked the committees and noted the report for assurance.

GOVERNANCE

Item 10: What assurance can be provided by the Audit & Risk Assurance Committee?

10.1 The Board considered an assurance report provided by the Audit & Risk Assurance Committee (ARAC). The ARAC met on 31st October 2022 and considered a presentation on how the Agency is responding to an inspection by the Health and Safety Executive (HSE); progress in implementing the National Audit Office's (NAO) recommendations; the next steps and timetable for revising the Agency's Risk Register and considered the Agency's financial performance; and considered an update on Internal Audit's work and reviewed the Agency's approach to responding to complaints.

10.2 The Board noted that Health & Safety is a top priority of the Agency, and an action plan has been put in place to address issues which have been identified. The Board also encouraged the use of internal audit, to drive up value and quality. The Board noted the report for assurance 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 No other items of business were raised and the Chair closed the meeting.

ACTIONS FROM MHRA BOARD MEETING IN PUBLIC – 15th November 2022

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	
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	On agenda
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.	John Taylor	21/02/23	
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	
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~~ 21/03/22	
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	
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	
83	21/06/22: A report on stage 1 and 2 complaints will be considered by the ARAC.	Michael Whitehouse	13/12/22	Completed – included in ARAC report
85	20/09/22: Follow up with Professor Lucy Chappell to understand how MHRA can work closely with NIHR to deliver the new Clinical Trials Legislation and guidance	Marc Bailey	15/11/22	Completed – this meeting has been arranged.
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	Verbal Update
87	20/09/22: John Taylor to provide a written response to the member of public who submitted a question regarding debt at the September Board	John Taylor	15/11/22	Completed.
New Actions				
88	Present a review of the Agency's Compliance Strategy to the Board	Laura Squire	21/02/23	

Medicines & Healthcare products Regulatory Agency

BOARD MEETING HELD IN PUBLIC

17 January 2022

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

- We announced new safety measures for valproate recommended by the Commission on Human Medicines, and work is ongoing with stakeholders to safely implement these
- We are participating in a new Life Sciences Council stakeholders' group to oversee development of a Roadmap for the new Medical Devices Regulatory Framework
- We continue to ensure timely licensing and updating of the latest COVID-19 products and ensuring vaccines are available which are effective against the COVID-19 variants
- The Regulators' Pioneer Fund established by the Department of Business, Energy and Industrial Strategy is supporting 3 MHRA projects aiming to unlock regulatory innovation
- We published guidance on the manufacture of cannabis-based products for medicinal use to clarify the MHRA and Home Office requirements and how these interrelate
- We co-led a successful global social media campaign, #MedSafetyWeek, to encourage people to report suspected adverse effects from healthcare products via Yellow Cards
- New interactive adverse reaction reporting presentations for COVID-19 vaccines went live, making data more accessible, a key milestone in the SafetyConnect program
- MHRA Services transformation planning has commenced with established medicines and new risk-proportionate processes will now be discussed with industry
- The MHRA has taken over the chair of the ACCESS Consortium of regulators of Australia, Canada, Singapore and Switzerland, and we continue to build international reliance
- We published the MHRA's Civil Service People Survey 2022 results internally which are now being analysed, and plans are being developed in partnership with staff to drive improvements.

SCIENTIFIC RESEARCH AND INNOVATION

Vaccine and blood products control testing

1.1 Scientists at our South Mimms laboratories have independently assessed key quality parameters of 263 batches of vaccines for the UK vaccination programme and have assessed blood products for the patient treatment. About 60% of these batches (158) underwent full laboratory testing. The team also tested 474 plasma pools which were used to manufacture blood products for the UK to confirm that they are free from contaminating Human Immunodeficiency Virus, Parvovirus B19 and Hepatitis A, B, C and E viruses.

Rotavirus vaccine guidance

1.2 The WHO informal consultation on the revision of the guidelines to assure the quality, safety and efficacy of Rotavirus vaccines incorporated MHRA contributions. Revisions such as this provide updated guidance for vaccine developers, manufacturers and control laboratories globally.

Cell therapies

1.3 At the recent WHO Expert committee for Biological Standardisation, the committee endorsed the first International Standards projects for cell therapy applications from scientists in the Biotherapeutics and Advanced Therapies Group. These standards will help ensure the consistency of stem cell-based therapies.

Mpox (formerly Monkeypox) research

1.4 A research reagent to assist the development and evaluation of methods to detect anti-mpox antibody has been made available for global distribution in the NIBSC catalogue via the Research and Development Vaccines Group. The material comprises convalescent plasma from individuals from Democratic Republic of Congo who have recovered from mpox infection. The project is part of our implementing partnership with the Coalition for Epidemic Preparedness Innovations (CEPI) for standardisation activities. This reagent will be instrumental for the evaluation of the immune responses to vaccines for mpox, and to understand the epidemiology of mpox outbreaks.

Marburg virus disease

1.5 We have received funding from the National Institute of Allergy and Infectious Diseases (NIAID) for the development of the first WHO International Standard for Marburg virus antibody. The standard will support evaluation of vaccines and therapeutics for Marburg virus disease. Convalescent plasma from Marburg viral infection survivors will be donated by Integrum Scientific and the Uganda Virus Research Institute (UVRI) and funded by CEPI.

Influenza candidate vaccine viruses

1.6 As a WHO Essential Regulatory Laboratory, the Pandemic Influenza team is currently generating Candidate Vaccine Viruses (CVVs) in response to recent human cases of swine influenza cases. These CVVs are at various stages of development, with one CVV having passed antigenic testing. Developing pre-pandemic CVVs is a key pandemic preparedness activity. Should a related influenza pandemic strike, these CVVs would be available to influenza vaccine manufacturers to enable the development and supply of vaccines to the public.

Innovative Licensing and Access Pathway

1.7 Two years on from the launch of the Innovative licensing and Access Pathway (ILAP), there have now been a total of 104 Innovation Passports granted and 20 Target Development Profiles produced. Work continues with ILAP partner organisations (NICE and other HTA organisations and the NHS) to ‘reset’ the ILAP integrated process in relation to the learnings to date, in particular the value of patient input and the role of Real-World Data.

HEALTHCARE ACCESS

COVID-19 vaccines and therapeutics

2.1 In November we approved the use of the COVID-19 vaccine developed by Novavax (Nuvaxovid) as a booster dose (homologous and heterologous) in adults. The COVID-19 vaccine developed by Pfizer/BioNTech (Comirnaty) was also approved as a booster dose for children aged 5-11 years, and a low dose version was approved for a primary series vaccination in infants and children aged 6 months to 4 years. In December we approved the Sanofi-Pasteur COVID-19 vaccine VidPrevtyn Beta, which is to be used as a booster dose in adults. This vaccine contains a version of the spike protein found on the surface of the Beta variant of the SARS-CoV-2 virus. It also contains an 'adjuvant', a substance to help strengthen the immune response.

2.2 In relation to COVID-19 therapeutics, the licence for Evusheld (a combination of two long-acting antibodies, tixagevimab and cilgavimab) was extended to include use for the treatment of COVID-19 in adults. The previously approved indication for Evusheld was for pre-exposure prophylaxis of COVID-19 in adults. Use of Evusheld for preventing COVID-19 is subject to a review by NICE (the National Institute for Health and Care Excellence).

Medicines for Group A Streptococcal infection

2.3 We have worked closely with the DHSC supply team to support manufacturers, pharmacies and the NHS to ensure supply of medicines to treat Group A Streptococcal infection. We have expedited review and approval of variations to existing licences involving medicines to treat Streptococcal A infections, and supported manufacturers of priority products on the regulatory steps to take to get these products to patients. We have used our regulatory flexibility to allow early patient access, where safe to do so, under medical supervision. We will continue to support DHSC work in facilitating patient access to these important medicines.

Prostate cancer medicines

2.4 Under the US FDA Orbis scheme to facilitate access to cancer medicines, a new indication was approved for Nubeqa (darolutamide) in the treatment of metastatic hormone-sensitive prostate cancer in combination with docetaxel. This provides improved access for prostate cancer patients of whom approximately 3,500 UK patients (7%) present with advanced or metastatic prostate cancer.

Cannabis-based medicines

2.5 In November, cross-Agency collaborative working led to the publication of guidance on the authorisations required to manufacture cannabis-based products for medicinal use as unlicensed medicines. Companies require authorisation by both MHRA and the Home Office, and each regulatory authorisation process requires some aspects of the other. The guidance comprises a 5-step process that has been agreed between MHRA and the Home Office which manufacturers should follow to apply for the necessary authorisations from each body. The guidance, in the form of a blog, has been well received by industry and has been referenced in publications, circulars and news posts within the industry sector.

Regulators' Pioneer Fund

2.6 We have received a major award from the Department of Business, Energy and Industrial Strategy (BEIs) Regulators' Pioneer Fund for 3 projects that aim to unlock cutting-edge regulatory innovation. This includes two projects that were jointly submitted by Software Group and the Clinical Practice Research Datalink, and one project from South Mimms scientists. One project will seek to develop approaches to make AI algorithms more interpretable using AI as a medical device as an exemplar so that clinicians and users have more confidence in either accepting or overruling an algorithmic decision. The second project aims to validate the use of high-fidelity synthetic data as synthetic control arms and to boost sample sizes in clinical trials. The third project will focus on developing guidelines to accelerate innovation for microbiome therapeutics and diagnostics.

Product information

2.7 Ensuring that accurate, up-to-date and accessible information is available to patients on the medical products they use is our patient information team's goal. In December we took part in a forum on 'reimagining product information for human medicines'. This event explored the challenges and opportunities for providing trusted medicines information in a variety of formats and distribution channels, aligned with the regulatory environment and in the context of the government's focus on overprescribing, interchangeable medicines, data and delivering a net zero NHS and is part of a wider project involving industry, healthcare professionals and the regulator on effective delivery of patient information.

PATIENT SAFETY

COVID-19 Vaccine reports

3.1 As part of our newly developed digital vigilance IT platform, SafetyConnect, we have developed a new format for publishing suspected adverse reaction reporting data for COVID-19 vaccines received through the Yellow Card scheme. This will be expanded during 2023 to all reports on medicines and medical devices. This new electronic format helps further meet our ambitions for greater accessibility and transparency of the information on which MHRA and its expert independent committees make their decisions.

Sodium valproate risk minimisation

3.2 Due to concerns that the current regulatory requirements for safe use of sodium valproate are not being consistently followed, and pregnancies continue to be exposed despite the Pregnancy Prevention Programme, new safety measures are to be introduced in the coming months for patients under the age of 55 years. Emerging data on male infertility and possible transgenerational effects of sodium valproate have led to new proposals for risk minimisation measures for male patients. The Commission on Human Medicines has established an implementation group to support the safe introduction of the new measures, including representation from across the healthcare system. The Group has advised a phased programme, which is currently under development according to patient safety priorities, in collaboration with the healthcare bodies to ensure ongoing patient care is not disrupted.

Lenalidomide Pregnancy Prevention Programme

3.3 Together with the British Generic Manufacturers Association and NHS, we have approved a single 'portal' for the Pregnancy Prevention Plan for generic lenalidomide, a medicine for the treatment of myeloma, a type of blood cancer, as well as for other cancers. The portal is a single UK-wide solution to support safe prescribing and dispensing of lenalidomide in the NHS. The portal allows prescribers and pharmacists to complete the Pregnancy Prevention Plan requirements for different suppliers of lenalidomide through the same portal. It has been designed to be easy to use and to provide an interactive interface, which is expected to both reduce administrative burden and increase compliance by healthcare professionals.

Infected Blood Inquiry

3.4 In November we contributed oral evidence to the Infected Blood Inquiry in its investigation into the circumstances in which men, women and children treated in the NHS were given infected blood and infected blood products, in particular since 1970. We provided evidence describing the role of the MHRA in the safety monitoring ('haemovigilance') of blood, blood components and blood products, including the mechanisms by which adverse events are collected, the principles of benefit risk evaluation and how MHRA engages and collaborates with other bodies to ensure the safety of blood, blood components and blood products.

Naloxone product defect

3.5 Naloxone is an emergency treatment for opioid overdose. After being notified of a limited number of Prenoxad (naloxone) packs in a batch marketed in France with missing needles, we issued a National Patient Safety Alert and a Class 4 Medicines Defect Information notice highlighting action to be taken. If no needles were present in the kit, there was a risk that patients, members of the public and/or healthcare professionals may not be able to administer life-saving doses of naloxone. We asked providers to contact individuals supplied with Prenoxad kits, where possible, and to support checks to ensure kits each contain two needles. This notification was shared with directors of public health and local drug and alcohol teams.

Promoting adverse event reporting

3.6 In November, we co-led a global social media campaign called '#MedSafetyWeek'. Regulators from 83 countries participated in joint messages to reach patients, carers and healthcare professionals to encourage reporting of suspected side effects from medicines. Our UK campaign encouraged Yellow Card reporting of safety problems including adverse medical device incidents. We provided extensive support materials including new social media animations, a new downloadable poster to put up in waiting areas or exhibition stands, and a digital poster for patient waiting area TVs, or screensavers. There was outreach through our stakeholders and networks including social media channels. Internationally, the #MedSafetyWeek hashtag reached 83 million people. We had 100 extra sign-ups to Drug Safety Update and the total number of Yellow Cards increased by 26% (775 reports).

Criminal Enforcement Unit

3.7 The Criminal Enforcement Unit has been engaging with numerous cross-sector partners to expand its internet intelligence and investigation capabilities. Several meetings have been scheduled with partners to identify opportunities for collaboration to tackle and reduce the online criminal threat.

PATIENT AND PUBLIC ENGAGEMENT

Patient Involvement Strategy

4.1 One year after publication of the Patient Involvement Strategy, the Patient, Public and Stakeholder Engagement team has compiled a report to outline progress. The report sets out MHRA ambitions, highlights some of our achievements over the year, and demonstrates how patient involvement can be incorporated across the MHRA. The report will be published early in 2023. A comprehensive patient and public involvement e-learning module has been launched and all staff have been asked to complete this by the end of March.

Customer Experience Centre

4.2 Over the past few months, the Customer Experience Centre's (CEC) enquiry volumes across all of its service areas have reached its highest levels since the team was established in 2020, 5500 enquiries a month, compared with 2020 when the monthly average was 3500. Vaccine quality, safety and efficacy topics have continued to comprise the majority our Freedom of Information requests with CEC offering significant assistance to agency experts in helping draft responses. We have also continued to strengthen our relationships with query handling teams at DHSC and UKHSA to share experiences and approaches to enquiry handling, in particular around mis/dis information on vaccines and Group A Streptococcal infection.

PARTNERSHIPS - NATIONAL AND INTERNATIONAL

Medical Devices regulatory framework

5.1 Following a proposal at the Life Sciences Council, an initiative has been launched by the Association of British Health Tech Industries (ABHI), the Office for Life Sciences, DHSC and the MHRA on developing a Roadmap for the implementation of the new regulatory regime for medical devices. Key themes are a pathway for innovative medical devices, approved body capacity, and international interoperability. In January, a roundtable meeting is being planned by ABHI to share the output of the HealthTRIP report which focuses on the challenges of small and medium enterprises with a particular focus on regulation. We are also engaging with industry on the five main themes of the draft In-Vitro Diagnostics (IVD) Roadmap.

ACCESS Consortium

5.2 From January 2023, the MHRA takes on the Chair of the Heads of Agencies of the ACCESS Consortium (the regulatory bodies of Australia, Canada, Singapore and Switzerland). The MHRA joined ACCESS in October 2020 and became a full member in January 2021. The role includes chairing the Heads of Agencies group which oversees various working groups which undertake work-sharing in relation to, for example, new active substances, generics and biosimilars. In 2021, ACCESS published its first Strategic Plan 2021-24 and we look forward to continued progress in delivering this and in building international reliance.

International guidance and harmonisation

5.3 Compliance Team inspectors continued their support towards international harmonisation and the development of new guidance. November featured virtual attendance at the International Council for Harmonisation (ICH) meeting hosted in Incheon, South Korea as part

of the Expert Working Group working on the revision to ICH E6 Good Clinical Practice (GCP), which is addressing the application of GCP principles to the increasingly diverse trial types and data sources being employed to support regulatory and healthcare related decision-making on medicines, and provide flexibility whenever appropriate to facilitate the use of technological innovations in clinical trials. Support was also given to the training of Good Laboratory Practice (GLP) inspectors at the regular OECD GLP Inspector training workshop held in Montreal, Canada. Inspectors from the MHRA delivered training relating to Data Integrity and the application of critical thinking to inspection conduct

Scientific communication and collaboration

5.4 Scientists attended a number of external meetings and conferences to communicate the science undertaken by the Agency and its impact on patients and the public. This included meeting with the University College Hospital London (UCLH) Rheumatology Research Patient and Public Involvement group to discuss research carried out using samples provided by UCLH patients; presenting the research of the MHRA Research and Development team and the work of the UK Stem Cell bank at the UCL Advanced Therapies Continuing Professional Development course; and a number of international conferences. Scientists attended international meetings on vaccines, including the WHO Polio Research Committee to discuss progress with the novel oral polio vaccine rollout; and at WHO International Standards meetings for development of SARS-CoV-2 vaccines.

Intelligent Automation

5.5 We presented and led discussions at the International Society of Pharmacovigilance Intelligent Automation Meeting, on the use of machine learning assisting with case processing during the pandemic and future plans under the SafetyConnect programme. Participants included other international regulators and senior industry stakeholders.

DYNAMIC ORGANISATION

Transforming MHRA services

6.1 Work is now progressing on MHRA service transformation, focussing initially on established medicines where a range of ideas are now being discussed with the pharmaceutical industry. We are also providing guidance to industry on how to make best use of existing options such as the self-certification process for labels and leaflets. We hosted over 40 delegates for a workshop entitled ‘What Makes a Good Quality Application?’ The workshop shared some of the common causes of validation errors in applications for marketing authorisations and variations. Feedback was also provided on the most common major objections seen in marketing authorisation applications as well as the most common concerns and validation issues that lead to delays in procedures or additional ‘Request for Further Information’ letters.

Regulatory Management System

6.2 Work is progressing at pace on the major technology build of the new Agency Regulatory Management System (RMS) which will replace end-of-life systems such as Sentinel and Lotus Notes. The RMS project has completed the discovery phase and options are being developed to enable an evidence-based decision around the definition of the Minimum Viable Product, projected for delivery in 2023. Good progress is being made to define the data foundations for the technology platform, which is fundamental to the next phase of work.

Quality audit for diagnostics

6.3 The Science, Research and Innovation Group underwent an audit to review the ISO 13485:2016 certification held for the design, manufacture, batch release, storage, and dispatch of in vitro diagnostic devices (IVDs). This Quality Management System applies to all products that are produced as control materials for diagnostic assays and fall within the scope of the IVD Directive 98/79/EC and more recently, IVD Regulation. In accordance with the Directive, IVDs must be CE marked to be freely marketed anywhere in the EU/EEA without further control. The audit had a good outcome with positive feedback on the scientific work and adherence to the standard. Five non-compliances were received and some verbal feedback on improvements that could be made, particularly related to continued work required following the organisational change.

Annual Civil Service People Survey

6.4 The results from the Annual Civil Service People Survey 2022 have been received and were published internally within the Agency. There is an overall analysis and drill down analyses for each of the Groups. The results indicate a mixed picture across the organisation. Our overall Engagement Index score for 2022 is 49%, which is disappointing as it is slightly lower than our 2021 score of 51%. This has been a difficult year and across government all the main survey themes have fallen in most Departments. As an Agency we have faced additional challenges and continue to do so.

6.5 The survey results, including the anonymous free text feedback, will be further analysed and shared for consideration by the People and Culture Committee. Chief Officers together with their senior management teams, the People Survey Focus Group and other representative staff networks such as the Inclusion Group will also consider the results and plan next steps. We will be engaging with staff to develop related plans and to play a part in driving improvements, regularly updating on progress in this area.

MHRA People Strategy

6.6 On 6 December following extensive internal consultation our first MHRA People strategy was launched to staff. This comprises five inter-related themes comprising: attracting and retaining the best people, developing exceptional people and people leaders, valuing diversity and promoting wellbeing and inclusion, investing in a healthy culture, and enabling great performance and delivery. The plan is to encourage feedback from our staff and publish a final version by April 2023.

FINANCIAL SUSTAINABILITY

Fees consultation

7.1 We have completed the consultation on the introduction of revised statutory fees, and following analysis of the 100 responses, work is progressing on the new fee orders comprising two UK wide statutory instruments (SIs) on Medicines, Medical Devices and Blood Components. We have prepared a consultation response which we envisage will be published within the coming weeks. Following completion of the Fees revision, work will begin on the next stage of our Fees and Charges strategy.

AGENCY PRIORITIES

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

i. Delivering cutting edge science to support and accelerate development of, and access to, new products for patients, making UK an attractive environment to develop and deploy innovative healthcare products

ii. Transforming our services in parallel with the strategy to replace our legacy IT systems with the new platform, the Regulatory Management System

iii. Competing and publishing our one-year review of the progress in delivering the Patient and Public Involvement Strategy

iv. Further developing our national and international partnerships, in the context of the regulatory reform agenda.

v. Taking full opportunity of the new People Strategy and develop proactive plans to address the results of the People Survey to drive improvements for staff and make the MHRA an excellent place to work.

Dr June Raine, CEO
January 2023

Medicines & Healthcare products Regulatory Agency

BOARD MEETING HELD IN PUBLIC

17 January 2023

Title	**What was the financial and people performance of the MHRA for the year up to 30 November 2022?**
Board Sponsor	John Taylor
Purpose of Paper	Assurance

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

1. Executive Summary

1.1 The operational surplus up to the end of November is £5.2million year-to-date (YTD), compared to a budgeted deficit of £0.2million. This is mostly the result of an underspend of £8million on staff costs as we have had slower recruitment into the new structure than planned and reduced income as a result. We are forecasting for the operating surplus to reduce in the second half of the year to £1.9million.

1.2 When looking at the total spend against funding the Agency is showing an underspend YTD of £11.5million. In addition to the Operating surplus this is due to the £6.9million underspend against our capital funding most of which is due to timing differences. Work on both the Regulatory Management System (RMS) and investment at our South Mimms site are forecast to ramp up in the second half of the year reducing this to an underspend of £0.7million on our capital funding by the end of the year.

1.3 Our customer debt is still higher than it should be. Although 40% of the debt is less than a month old it is concerning that 38% is over 6 months old and the focus is very much on ensuring that this is reduced before the end of this financial year.

1.4 The people resource within the Agency is critical in terms of capability, capacity and 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 at the end of December had 142 vacancies in the recruitment process (advertisement through to appointment with an agreed start date).

2. WHOLE AGENCY PERFORMANCE

November 2022	This YTD Actual £M	This YTD Budget £M	Variance vs Budget %	This Year Forecast £M	This Year Budget £M	Variance vs Budget %
Trading Income	81.5	85.5	(5%)	123.4	128.1	(4%)
Income from DHSC	18.3	18.3	0%	27.5	27.5	0%
TOTAL INCOME	**99.8**	**103.8**	**(4%)**	**150.9**	**155.6**	**(3%)**
Staff Costs	51.9	59.9	13%	79.8	90.5	12%
Operating Costs	42.7	44.1	3%	69.3	66.6	(4%)
TOTAL EXPENDITURE	**94.6**	**104.0**	**9%**	**149.1**	**157.1**	**5%**
OPERATING SURPLUS	**5.2**	**(0.2)**		**1.9**	**(1.5)**	
Spending Review Revenue	4.7	4.7	0%	7.0	7.0	0%
CPRD Revenue Funding	0.7	0.0	0%	1.8	0.0	0%
TOTAL EXTRA REVENUE FUNDING	**5.3**	**4.7**	14%	**8.8**	**7.0**	26%
Change Costs	6.0	5.8	(3%)	9.3	6.5	(42%)
TOTAL REVENUE CHANGE COSTS	**6.0**	**5.8**	**(3%)**	**9.3**	**6.5**	**(42%)**
TOTAL REVENUE SURPLUS	**(0.6)**	**(1.1)**		**(0.4)**	**0.5**	
Spending Review Capital	6.9	6.9	0%	10.4	10.4	0%
DH Capital Funding	4.7	4.7	0%	7.0	7.0	0%
TOTAL EXTRA CAPITAL FUNDING	**11.6**	**11.6**	**0%**	**17.4**	**17.4**	**0%**
Change Costs	4.1	6.4	37%	14.9	16.6	10%
CPRD Change Costs	0.7	0.0	0%	1.8	0.0	0%
TOTAL CAPITAL CHANGE COSTS	**4.7**	**6.4**	**37%**	**16.7**	**16.6**	(1%)
TOTAL CAPITAL SURPLUS	**6.9**	**5.2**		**0.7**	**0.8**	
TOTAL SURPLUS (incl. REVENUE & CAPITAL	**11.5**	**4.0**		**2.1**	**(0.2)**	

Income

2.1 Year to date (YTD) income is £81.5million, £4million (5%) below budget. There are two principal drivers of this shortfall. The first is that at the start of the year it was accepted that fee assumptions for 2022/23 required uplifting due to the volumes of work in Healthcare Quality & Access (HQ&A) highlighting the need for additional resource. These additional staff are now largely in place and are in training, but the impact is not yet being felt on fee income. The second is lower than budgeted sales of products by Scientific Research and Innovation (SR&I) due to lower demand.

2.2 The income position against budget improved during November by £0.5million because of a rise in Periodic Fee income which is now forecast to be higher than the budget for the year.

Staff Costs

2.3 Staff costs are £8million (13%) under budget for the YTD due to staff vacancies within the Agency.

2.4 We had originally budgeted for vacancies to improve from 13% in Q1 to 8% in Q2 and the remainder of the year as we completed transformation. However, we have instead seen the number increase with the current vacancy rate rising to 17.1% from the Q1 average of 14.8%. This resulted in an underspend in November of £1.1million on staff costs. The Digital & Technology (D&T), Safety & Surveillance (S&S) and Science Research & Innovation (SR&I) groups being the worst affected. Please see the People Performance, Section 3 below, for the actions that we are taking to address recruitment and retention.

Change Costs

2.5 Change costs are currently £1.5million under budget (revenue spend £0.2million over and capital spend £1.7million under), driven by YTD underspends in transformation, redundancy, and the Regulatory Management System (RMS). However, with the exception of redundancy costs, most of these underspends are time variances, and we expect the spend run rate to increase towards budget in the coming months. This includes the spend on RMS which will pick up following the completion of the discovery phase. Any remaining underspends will be offset by approved overspends in SafetyConnect and Finance Transformation. Overall, we are expecting the change costs to be in-line with budget by the end of the financial year.

Capital expenditure

2.6 We have £6million of baseline capital funding from DHSC to support the running of our South Mimms site. Of this we have spent £0.78million YTD but are forecasting to spend £5.8million by the year end. Profiling the capital spend to the last quarter of the year follows the same pattern of spend as last year, so this is not unrealistic. We have developed a more robust pipeline of the capital requirements at South Mimms to ensure that we can commission and start work earlier next year.

2.7 We were awarded £9million of capital as part of the Spending Review to start work on the new Regulatory Management System (RMS). Of this we have spent £2.59million YTD. We plan to increase spend significantly in the last months as resources ramp up following the completion of the discovery phase and we expect to spend all of the budget.

2.8 There is sufficient capital funding from DHSC this financial year to cover our needs. We are currently negotiating our capital requirements for next year, particularly the scaling up of work on RMS, with the DHSC.

Customer Debt Levels

2.9 The table below shows the Agency had debt of £12.0million owed to it at the end of November. This has improved by just over £70,000 from the £12.7million reported to the Board at the end of September.

Aged Debt	Total	% of Total
0-30	4,860,846.87	40%
31-60	548,430.08	5%
61-90	827,608.95	7%
91-180	1,243,450.87	10%
181-360	2,646,782.04	22%
360+	1,943,704.20	16%
Total	**12,070,823.01**	**100%**

2.10 It should be noted that 40% of this debt is less than a month old. However, a growing concern is that we now have £4.6million (38%) of debt over 6 months old of which almost £2million is over a year old. Work on this older debt is now a priority for the team to clear before year end. We have appointed an additional four interim credit controllers to work through the debt ledgers. We are also working on a new debt collection contract for referring debt where all our internal avenues have failed.

2.11 The Income Collection Policy, which aims to minimise the customer debt that the Agency carries, has now been published. The team are planning meetings with all revenue generating teams to talk through how they will adopt the new requirements. However, it will take time to make processes and systems conform to the new policy and so we will continue to focus our attention on centralised debt collection.

3. People Performance

3.1 Prioritisation of recruitment continues, with weekly updates to the Executive Committee on all newly launched recruitment campaigns and no backlog in terms of central recruitment related activities.

3.2 A review of the length of time taken to onboard appointees and specifically the required security checks, has led to a decision to reduce the timespan for references from the Civil Service guide of 5 years to 3 years (NHS norm).

3.3 By the end of December (updated figures as the position is changing daily) 142 vacancies were in the recruitment process (advertisement through to appointment made with an agreed start date). It should be noted that approximately half of the posts which are not being actively recruited into are covered by fixed term or contingent staff and the intention is not to actively recruit permanent staff at this time for a variety of reasons.

3.4 We currently have 1,123 Full Time Equivalent (FTE) people filling 1,387 (FTE) posts.

3.5 The other main area of focus on people continues to be the current level of voluntary turnover. Annualised voluntary turnover is 17.1% over a rolling 12-month period. This excludes voluntary exit and voluntary/compulsory redundancy linked to the reduction in posts, as well as dismissals. It includes permanent staff and fixed term contract staff who have left before their original fixed term contract end date. Reasons for leaving continue to be largely identified by individuals as pursuit of career opportunities or personal reasons. 15% of leavers transferred within the civil service and 3.4% (12) were due to retirements; double the average of the previous two years. Across the civil service the average turnover figure has now increased to 15% and the Chartered Institute of Personnel Development (CIPD) report a "healthy" turnover as between 10% and 15%.

3.6 The main issue for the agency continues to be vacancies in combination with underlying turnover, as a result of a range of internal and external factors including the recruitment market in general and the competition from both the civil service and industry for talent that the Agency faces. See paragraph 3.8 below for the parallel activities that will improve recruitment and retention in the short and longer term.

3.7 In November 23 people left the agency and 48 people joined the agency which demonstrates a continuing, albeit slight, shift in the balance.

3.8 While short term resourcing priorities remain the focus, parallel people related work also continues. This includes:

- talent management, including the development of a graduate scheme and apprenticeship expansion plans
- the further development of systematic workforce planning
- the publication of a Career Development Guide
- a Culture Action Plan and related focus group and monitoring of progress
- the first stage review of the Career Development Framework (CDF), extending the range of roles to which this is applicable.

3.9 The new people strategy "Putting our People First" was launched in the All Staff Meeting in early December and this includes the full range of people related issues, with clear plans and indicators for measuring progress. The intention is for this to drive forward the stated aim for the Agency to be a great place to work.

3.10 The feedback from the annual Civil Service People Survey (launched at the end of September 2022) was received in early December. The high-level results indicate a mixed picture across the organisation. The overall engagement index score for 2022 is 49%, which is disappointing as it is slightly lower than our score of 51% from 2021.

3.11 The results will be further analysed and shared for consideration by the People and Culture Committee in January 2023. Chief Officers together with their group Senior Management Teams (SMTs), the People Survey Focus Group and other representative staff networks such as the Inclusion Group will also spend time considering the result and next steps.

3.12 There will be engagement with staff to develop related plans and to play a part in driving improvements, with regular updating on progress in this area.

3.13 Results for all Civil Service departments and agencies will be published on GOV.UK in the new year.

3.14 Annualised sickness (both long term and short term) was 6.8 average days by FTE (rolling 12-month period), a slight increase over the previous report. There is generally an increase at this time of year due to seasonal factors. The Civil Service average is 6.1 days (a range of 1.1 to 9.7 days (depending upon Department).

4 Group Performance

4.1 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 agreed and will be used for the segmental analysis in the 2022/23 statutory accounts and reflected in the third quarter management accounts in January.

Scientific, Research and Innovation

November 2022	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 Income (£M)	4.4	4.7	(5%)	34.6	37.4	(8%)	52.9	56.1	(6%)
Total Costs (£M)	1.9	2.0	6%	14.0	15.6	10%	22.7	23.5	3%
Total Operating Surplus (£M)	**2.6**	**2.7**	**(4%)**	**20.6**	**21.8**	**(6%)**	**30.2**	**32.6**	**(7%)**

4.2 SR&I are £2.8million (8%) below their sales budget YTD. This results from a range of factors. The main one is that the income from the sale of reference materials, contract filling and control testing is £3.3million below budget YTD. The lower than planned sale of reference materials, particularly flu reagents, is the main cause of this and we need to assess how this reduction, if sustained, should be reflected in our income budget next year. An uptick in sample testing income against YTD budget of £0.6million has helped to mitigate the shortfall.

4.3 YTD expenditure is £1.6million below budget, mainly because of lower expenditure in lab costs that reflects lower income generating activity in grants and contracts work and also lower staff costs.

4.4 We forecast SR&I to finish at a small underspend in expenditure due to lower lab consumables and services and staff costs. However, the underspend against Operating Costs is not enough to compensate for the significant forecast loss in income so it is expected that SR&I will finish the year with an operating surplus £2.4million (7%) below planned.

Healthcare Quality and Access

November 2022	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 Income (£M)	4.3	3.8	11%	29.2	31.3	(7%)	43.9	46.7	(6%)
Total Costs (£M)	2.4	2.7	12%	19.2	21.0	9%	29.0	31.7	8%
Total Operating Surplus (£M)	**1.9**	**1.2**	**64%**	**10.0**	**10.3**	**(3%)**	**14.9**	**14.9**	**0%**

4.5 Income in November was £0.5million (11%) above budget because of the transfer of COVID grant funds to the relevant team and strong Blood Compliance income. The YTD position is £2.1million (7%) behind budget. However, this needs to be seen in the context of the decision recognising the need to recruit to reflect revised income forecasts, was only made in April 2022. Recruitment has since been prioritised with 8 new starters now in training and a further 4 – 6 identified through a more recent campaign. The lesson that for resources to have a full year impact on income, decisions need to be made well ahead of the start of the year, has been learned and factored into the planning process for 2023/24. Following training of new staff, we expect the income run rate to increase in the following months.

4.6 In terms of expenditure, HQ&A continues to underspend because of the impact of staff vacancies on staff costs. However, this month sees some critical HQ&A appointments including a new Deputy Director Population Health (who will lead on Generics performance), completing the senior leadership team, and multiple appointments in Innovative Devices to support the delivery of the new regulatory framework. Travel and subsistence costs are also lower than budgeted in the Inspections teams as fewer international inspections have been carried out. HQ&A is forecast to end the year with a balanced budget as the underspend compensates for the income under-performance.

Safety and Surveillance

November 2022	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 Income (£M)	2.5	1.5	64%	12.7	12.4	2%	20.5	18.7	10%
Total Costs (£M)	2.2	2.3	7%	15.3	18.2	16%	23.9	27.4	13%
Total Operating Surplus / (Deficit) (£M)	**0.3**	**(0.8)**	**136%**	**(2.6)**	**(5.8)**	**55%**	**(3.4)**	**(8.7)**	**61%**

4.7 Safety and Surveillance income is ahead of its YTD budget because of higher Variations income. This, however, is due to a mismatch between Variations income actuals and budgets allocated to S&S and HQA as part of the restructuring of the Agency. The change in allocation for Variations income has been agreed with Chief Officers and will be adjusted in the Q3 management accounts.

4.8 S&S income will also be adjusted (budget and actuals) at the end of December to distribute the Periodic Service Charge, which has been held centrally until the appropriate allocation between the new groups had been agreed. Income will also be adjusted for a proportion of the Devices DHSC funding (budget and actuals) reflecting the work carried out on devices within S&S. Once these allocations have been completed, S&S will no longer be in an operating deficit.

4.9 S&S staff costs are significantly (20%) below budget because of the high number of vacancies across most teams. However, we have had a high number of starters in December and January with a large number of posts in recruitment. There is also recruitment of fixed term and contingent labour in the second half of the year to deal with backlogs.

4.10 YTD Non-Pay costs are at budget as lower spend on Contracted Out Services in Patient Safety Monitoring (PSM) is making up for higher IT spending in CPRD due to unexpectedly higher inflation-related increases and the falling value of the GB Pound against the US Dollar for Azure. PSM costs are forecast to increase in the coming months as the team has more capacity to dedicate to planned projects.

Non-fee earning Groups

4.11 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.

November 2022	Period Actual	Period Budget	*Variance vs Budget* %	YTD Actual	YTD Budget	*Variance vs Budget* %	Full Year Forecast	Full Year Budget	*Variance vs Budget* %
Total Income (£M)	2.9	3.4	(15%)	28.5	27.4	4%	41.2	41.1	0%
Total Costs (£M)	6.8	6.3	(8%)	46.1	49.2	6%	74.9	74.4	(1%)
Total Operating Surplus (£M)	**(3.9)**	**(2.8)**	**(37%)**	**(17.6)**	**(21.8)**	**19%**	**(33.7)**	**(33.3)**	**(1%)**

4.12 £26.5million of the YTD income is from the Periodic Service Charge. The full amount that we earn is only know later in the year when companies have provided us with their medicines sales data, and we have agreed the commensurate reductions in their annual charge. Because of the uncertainty of this income, we recognise one twelfth of the budgeted income each month in our management accounts. During October our forecast model for this income showed that we will outperform our budget by c£3million this year which we will include in our forecast for Q3. We have also recognised some of this additional income and are now £1.2million ahead of our YTD budget of £25.3million. From Q3 this income will be allocated out to the fee-earning operations groups, where the services that it pays for are provided, in HQ&A and S&S.

4.13 Costs are £3.1million (6%) below YTD budget. This is a mixture of under and overspends. The largest of these are within Digital & Technology which has an underspend of £4.8million (23%) YTD both as a result of staff costs and technology services. The latter, which is £3.5million underspent YTD, is in part due to timing differences which will reduce in the final quarter of the year. The main overspend is £2.3million YTD in Corporate. This is because of higher depreciation costs and accommodation costs. We have had to expense the remaining fit-out costs for the 5th and Ground Floor at Canary Wharf which we have vacated and continue to pay for the vacated half of the tenth floor. We expect to stop paying for this by the end of January.

John Taylor
January 2023

Medicines & Healthcare products Regulatory Agency

BOARD MEETING HELD IN PUBLIC

17 January 2023

Title	**What assurance can be provided by the Audit Risk and 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 Chair and regular attendees of the Audit & Risk Assurance Committee (ARAC) met informally on 13 December 2023. For valid reasons the Committee was not quorate, but no formal decisions or recommendations were made to the Board requiring all Non-Executive Members to be present.

1.2 The attendees received an update on progress in addressing the issues raised by the Health and Safety Executive at the South Mimms site; we reviewed progress in responding to external audit's recommendations; and considered the Agency's current financial performance. The recently appointed Risk Manager set out her plan and timetable for enhancing the Agency's approach to risk management. We considered four Internal Audit reports on: the Innovative Licensing Access Pathway (ILAP); Financial Controls; Payroll; and Compliance with Cabinet Office Spending Controls.

1.3 The attendees reviewed the National Audit Office (NAO) and KPMG plan for their audit of the MHRA's 2022-23 Financial Statements and the Agency's timetable for producing its annual report to meet the Parliament's statutory timetable. Finally, the Agency's most recent complaints report was considered.

2. Health and Safety

2.1 We were assured that the Agency is working to address the issues identified by the Health and Safety Executive (HSE) and that progress is being made. HSE has extended the target date to April 2023 by which the Agency has to provide evidence that it has a clearly defined policy to manage organisational change and in particular to manage effectively risks to health and safety from such change. A new specialist member of staff will join the Agency at the beginning of January to lead the work to ensure that the Agency retains its SAPO (Specified Animals Pathogens Order) license. We will receive a written report on progress at our next meeting on 2 February.

3. External Audit Recommendations

3.1 We were assured that the Agency has or is implementing the recommendations to remedy the issues identified by the NAO and KPMG during their final audit of the 2021-22 financial statements. External Audit confirmed that as set out in the paper presented to ARAC, progress was encouraging and in particular the enhanced controls over bank and other reconciliations. More evidence as to how these improvements are working in practice is needed and we will be receiving further assurance at our February meeting (paragraph 5.3 below).

3.2 We asked whether the Agency's projected income and expenditure estimates to 31 March 2023, which were presented to the Board in November, remained on track. We

were told that income had increased (largely from the Service Charge levied by the Agency) and that expenditure remained broadly as planned. Finance's current projection is that operationally the Agency should be in surplus at the year end. We were encouraged by this but emphasised the importance of all divisions across the Agency meeting their agreed spending plans or where this is unlikely that they release funds early enough for budgets to be reallocated to ensure that funds are used cost-effectively to advance the Agency's priorities.

4. Risk management

4.1 The Agency has recently appointed a new specialist Risk Manager who is leading the work to enhance the MHRA's risk management. We received a comprehensive presentation on the key actions planned over the next eight months. This builds on the Board's September discussion of strategic risks. ARAC supports this important work and we are encouraged by the particular emphasis on engaging the Agency's people on the design of risk management to ensure that the process for staff to report risks is clear and easy to do.

4.2 To support this work, we discussed three requirements which we consider important:

(i) The risk enhancement programme will continue into the next financial year. It is important however that the Agency can demonstrate that throughout the current financial year it has had in place effective arrangements to manage risk. This needs to be set out in the Governance Statement which the Accounting Officer includes in the Annual Report.

(ii) Risk management needs to be supported by an appropriate culture. Risk is as much about staff being confident that they can be innovative in the interests of patients knowing that associated risks are being managed effectively as it is about mitigating the risk of adverse consequences. Both are important. The Agency's risk appetite statement needs to reflect this balance.

(iii) The Agency's strategic risks can be broadly categorised as internally and externally focused. The former are largely those that are concerned with ensuring the Agency's long term resilience such as its digital capability and its ability to recruit and retain skills. External risks are more about how the Agency works with partner organisations as part of the wider health ecosystem, how the Agency maintains public trust, and the effectiveness of how the Agency discharges its regulatory responsibilities to promote patient safety while also helping supporting innovation to maximise the UK's access to new medicines and medical devices. ARAC consider that in presenting strategic risks to the Board the distinction between internal and external risks should be highlighted to enhance assurance as to how risks are being mitigated.

4.3 The Committee will receive a further update on progress on the risk management enhancement programme at its February meeting. The intention is also that the existing Risk Register will be presented to the Board at a subsequent meeting to provide additional assurance on current arrangements.

5. Internal Audit

5.1 We considered four reports from Internal Audit:

Innovative Licensing and Access Pathway (ILAP)

5.2 This received a Limited assurance assessment. The report recognises the significant impact and ongoing potential of ILAP to accelerate patient access to medicines. The report also acknowledges the speed "in flight" at which ILAP was developed. This reflects well on the Agency's drive and agility. The limited assessment reflects the way in which ILAP has subsequently been rolled out and the need for better governance. The Agency with its investment board and associated controls has the necessary processes and procedures to ensure good governance. The key systemic lesson from the Internal Audit's report is that these need to be consistently applied even when the Agency is working at speed.

Financial Controls

5.3 This received a Moderate assessment. We were encouraged by this, but in light of the difficulties encountered in finalising the Agency's 2021-22 Financial Statements, we are seeking further assurance. This will be provided through an assessment which the Deputy Director of Finance is leading to evaluate how well the Agency complies with the Government Finance Profession's functional standards. The assessment will be independently validated by Internal Audit, and we will consider the outcome at our February meeting.

Payroll

5.4 This received a Limited assurance rating. We are concerned by the assessment and in particular evidence that reconciliations to ensure the accuracy of staff in post have not been consistently applied. We welcome the assurance from the Director of Human Resources that remedial action is underway. We emphasise that this must be a priority for the Agency. Staff must have confidence that payroll is operating effectively. Control weakness in such a key function, if not addressed quickly with the necessary improvements, could have implications for the assurance work which External Audit needs to undertake to support their audit opinion.

Compliance with Cabinet Office expenditure controls

5.5 This received a Moderate assessment. The only issue is the need for the Agency to clarify its medium-term digital spending projections, which is being addressed.

5.6 We briefly considered progress in implementing Internal Audit's recommendations. We will return to this at our February meeting when the Agency should have action plans for implementing all of the recommendations in the reports considered at this meeting.

5.7 We received assurance from Internal Audit that they would be able to carry out sufficient work in the remainder of this financial year to provide their annual governance assurance

to the Accounting Officer. The ARAC Chair has a meeting scheduled early in 2023 to discuss priorities further with the Accounting Officer and the Director of Internal Audit.

6. External Audit Plan and Annual Report timetable.

6.1 We reviewed the NAO and KPMG's plan and fee for the audit of the MHRA's Annual Report and Financial Statements for 2022-23. On behalf of the Agency, we also provided the necessary assurances required by external audit of the Agency.

6.2 We reviewed the Agency's plan and timetable for ensuring the completion of the Annual Report to meet the statutory timetable for laying these in Parliament. We fully endorse the aim to present to the Board an audited Annual Report and Financial Statement rather than having to delegate responsibility to the ARAC Chair to resolve outstanding issues on behalf of the Board as has become standard practice. We were assured that the plan if met would enable the Agency to deliver to the Board fully audited accounts. We suggested however that the plan should be stress tested and in particular Finance and HR should consider now if there is any likelihood of external approvals being required from the Treasury or Cabinet Office which could take more time and put the timetable at risk. We will continue to monitor progress with the plan.

7. Complaints Handling

7.1 We considered an update on the number of complaints received by the MHRA. We were assured that these are being handled in a timely manner. We noted the increase in correspondence that raises issues which the Agency cannot resolve and support the need to consider how best to respond to such correspondence.

Michael Whitehouse
Chair of Audit & Risk Assurance Committee
December 2022

Medicines & Healthcare products Regulatory Agency

BOARD MEETING HELD IN PUBLIC

17 January 2023

Title	**How will the new MHRA People Strategy improve the recruitment, diversity, development and retention of our staff to deliver our statutory responsibilities?**
Board Sponsor	June Raine
Purpose of Paper	Assurance

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

1. Executive Summary

1.1 Following extensive consultation, approval by the Executive Committee (ExCo) and launch of the "Putting our People First" people strategy on 6th December 2022, a reflection 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. Also, 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.

1.2 The title of the people strategy echoes that of "Putting Patients and the Public First", recognising our people's role in achieving this and highlighting the essential contribution of the agency's people in achieving the future corporate plan. Similar linkages will be evident in terms of the developing science and data strategies, which will contribute to the identification of people resourcing requirements. The document is intended to provide a high level, three-year strategy which parallels the new corporate plan and will be reviewed and revised to take account of emerging intelligence and priorities. Various more detailed people plans are referenced.

1.3 The "Putting our People First" people strategy will be published externally alongside the agency corporate plan and having been published internally, the document is also being made available in advance to all Board members. The purpose of this paper is to make reference to the people strategy broader context, with more specific focus on the issues of recruitment, diversity, development and retention. It seeks to provide assurance in these respects, whilst also welcoming any requests for clarification or valuable further contributions to the strategy and plans.

2. Introduction

2.1 The people strategy has been designed to set out our longer-term strategic intent and related plans, demonstrating both the commitment of the agency and the expectations we have of people themselves to contribute to our shared aims. The strategy links to further detailed documentation, such as the Culture Action Plan and the key performance indicators within this strategy and those linked documents provide the basis to monitor progress and for ongoing reflection of any related learning. The people strategy is a living document and a reflection of the commitment of ExCo as individuals and a team in leading and driving forward progress in this priority area. As such it will be reviewed, updated and progress monitored, with the People & Culture Committee taking a lead role in seeking and providing assurance.

2.2 The strategy itself extends beyond the four specific issues referenced in the title of this paper and reflects the need for a holistic approach, with many overlaps and connections between people related initiatives. The structure of the document and a brief summary of the focus is as follows:

2.2.1 **Attracting and retaining the best people**

The agency's future and related ambitions and plans depend upon the ability to source and retain people with the talent, capabilities, potential and motivations needed to deliver the agency's plans. Key to this is the requirement for an integrated workforce plan and related activity.

2.2.2 **Developing exceptional people and people leaders**

There is a clear need to develop and support our people to be the best they can be both within and potentially beyond their current role, recognising differences in learning styles and opportunities and extending beyond formal training to wider forms of learning. Given the critical role of leaders in the delivery of all elements of the people strategy, there is additional value in investing in this group to maximise the chances of success.

2.2.3 **Valuing diversity and promoting wellbeing and inclusion**

One of the Agency's strengths is its diversity and our recognition that the more diverse our people, the better our decision making, as decisions reflect the diversity of the public and their health needs. There is always more work to be done in order to be a truly inclusive organisation and similarly in our commitment to promoting the wellbeing of our people.

2.2.4 **Investing in a healthy culture**

The necessity for the agency transformation to include significant changes in culture was recognised at the outset, as was the need to work together to co-create and maintain a workplace which actively promotes the requisite culture and thereby improves performance in the context of being a great place to work. This then remains a priority.

2.2.5 **Enabling great performance and delivery**

With the new One Agency structure now designed and largely populated, the focus is shifting to what needs to be in place to enable all of the agency's people to meet those ambitious delivery expectations and plans. this includes developing governance and decision making frameworks.

2.3 As demonstrated above there is an inter-relationship between all five areas identified within the strategy and even when the contribution is less obvious, there is an indirect impact and the need for that holistic approach. However, focussing in more detail upon those issues specifically identified by the board and the direct action the agency needs to take to improve upon:

2.3.1 **Recruitment**

It is recognised that this is a short-term priority for the agency right now and efforts in this respect have been escalated in recent months, with an expectation that vacancy levels and related recruitment activity will return to normal levels by the end of March 2023 as a result of this prioritisation. Related reporting, including activity, is included in the agency quarterly Performance report and monthly Finance & People reports. The strategy itself focuses on the period 1st April 2023 to 31st March 2026.

We are strengthening the workforce planning process introduced in summer 2022 to ensure that a dynamic and proactive approach is taken to address short and longer-term people requirements and the lead time required to support the introduction of new recruitment pipelines, including the expansion of our apprenticeship scheme and introduction of a new graduate scheme, are factored in.

Shared responsibility for making the most of potential sourcing opportunities, such as conferences, networking and social media and ensuring that the total package on offer is improved upon and communicated in a compelling manner, is intended to overlay improvements in recruitment process streamlining.

2.3.2 **Diversity**

An emphasis on psychological safety will add to ongoing efforts to promote diversity and equality of opportunity for all, to be a truly inclusive agency. A focus on areas identified by staff-led networks, within survey feedback and through people related metrics will increase understanding of aspects on which to actively concentrate our efforts. This will positively increase impact and requires everyone to actively contribute. Leadership opportunities in this space include championing roles which are currently under discussion.

Health and wellbeing initiatives add further to creating an environment where everyone can flourish.

2.3.3 **Development**

Leadership development goes hand in hand with professional learning and maintaining and developing technical skills and expertise in terms of the impact upon agency performance and outcomes and the intention is to focus on both. Learning opportunities will be broad ranging and include professional skills training, formal management and leadership development and the opportunity for matrix working and learning from colleagues within and outside of role and team.

Mentoring and coaching add further to the more individualised support on offer.

2.3.4 **Retention**

It is recognised that this is a parallel short-term priority for the agency right now and similar to the heightened vacancy levels and related recruitment activity, the impact of the agency reorganisation and external factors such as the external market, have led to an increase in turnover levels beyond that normally expected and anticipated to settle by the end of March 2023.

Related reporting, including activity, is included in the agency quarterly Performance report and monthly Finance & People reports. The strategy itself focuses on the period 1st April 2023 to 31st March 2026. However, feedback from staff themselves is and will continue to be sought to inform and this includes intelligence gathered in respect of people's career move intentions as well as leaver information.

Culture has a significant part to play in terms of making the agency a great place to work and affects how engaged people feel as individuals, as part of a team and ultimately as part of the agency. A focus on values and behaviours is intended to underpin progress already made in this area and set out in the published Culture Action Plan.

Feedback from staff remains an important way of establishing progress and identifying what more or different requires attention.

The total employment package on offer also impacts upon the attractiveness of the agency as a place to work in a challenging recruitment market and this includes, but is not limited to financial reward, recognition and opportunities for development.

While there are constraints in terms of financial offering, in terms of the agency's financial position and civil service limitations, the agency will continue to review opportunities to utilise competency related pay frameworks and use both in-year and annual pay award opportunities to target financial reward appropriately.

2.3.5 Each of the areas identified above, individually and collectively, is included within the people strategy and each section identifies specific targets to be achieved in the first year. Measures of success criteria included at the end of the document provide baselines and targets which will be monitored and reported on, and from which lessons will be learnt by way of any changes to approach required. A variety of fora will have a role to play in terms of the specifics of the implementation of the plans including People & Culture Committee, which has an overarching responsibility.

3 Proposal

3.1 As noted above, the “Putting our People First” people strategy has been extensively consulted upon, launched and published internally. This paper seeks to provide assurance in relation to an appropriate, ambitious people strategy which has the commitment of ExCo and is designed to be reviewed, monitored and updated throughout its duration.

4 Recommendation

4.1 The Board is asked to seek any further information, provide any contributions in terms of future plans and confirm assurance in respect of the people strategy.

Vanessa Birchall-Scott
January 2023

Medicines & Healthcare products Regulatory Agency

BOARD MEETING HELD IN PUBLIC

17 January 2023

Title	**What assurance can be provided by the Organisational Development & Remuneration Committee?**
Board Sponsor	Amanda Calvert
Purpose of Paper	Assurance

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

1. Introduction

The Organisational Development & Remuneration Committee (ODRC) met on 5th January 2023 with the following objectives:

- Review and discuss the actions and plans to improve employee satisfaction and motivation following the establishment of the new organisational structure.
- Review and discuss the progress in delivering the services that underpin the One Agency operating model and delivery of the business plan.
- Review the progress for delivery of the Regulatory Management System (RMS) programme.
- Review ODRC effectiveness

2. Plans to improve employee satisfaction and staff motivation

2.1. The committee recognised that everyone in the Agency has experienced an unprecedented level of change both in the external and internal environments. As people work through the change curve it is normal to experience a temporary drop in motivation, but it is essential that actions now help to build confidence and performance.

2.2. The Director of Human Resources presented a very comprehensive plan of the actions taken and plans to help leaders and all members of staff develop into their new roles and embrace new ways of working suitable to deliver the levels of service expected by external stakeholders.

2.3. It is recognised that recruitment of staff into new roles has been slower than planned and this has resulted in many existing staff experiencing very high workloads making it difficult to find time to plan and change to meet future needs.

2.4. The committee were assured that a substantial number of key roles have now been filled and that the Human Resources (HR) team believes the peak of activity has now been reached.

2.5. Data from the Transformation Gate 0 independent review indicated that the future vision was not well understood by many staff and many people were still unclear what the future held for them.

2.6. The committee discussed ways that the future vision could be “brought to life” so that all staff could feel part of the future. The agency has a very positive reputation externally and it was discussed how stories of the great work being done by teams throughout all areas of the Agency could be used to help communicate and inspire.

2.7. SafetyConnect was just one example of how new ways of working is helping people to find safety signals more effectively.

2.8. The One Agency Leadership Group (OALG) are key to helping shape the vision and they recognised that the Corporate Plan is an excellent vehicle to connect and communicate shared purpose to everyone in the Agency.

2.9. OALG and the Executive Committee (ExCo) supported by HR will work with teams to further develop and deliver the corporate plan which can provide a focus and tangible targets that everyone can feel they are contributing to in some way.

2.10. Staff retention was discussed. It was recognised that basic salary rates were substantially higher in the private sector, but that the Agency offered other benefits including excellent experience, training and development as well as being part of an internationally respected organisation that has a huge impact on public health. There is some opportunity to continue to build the MHRA 'brand'.

2.11. The people plan was welcomed but not discussed in detail as this is an item on the Board Agenda.

3. Progress on delivery of new services within the One Agency operating model

3.1. The committee welcomed the Director of Delivery to the meeting who has taken on the role of Senior Responsible Officer (SRO) for the Transformation Programme.

3.2. To date the Transformation Programme has been wholly associated with the organisational restructuring of the Agency rather than building an organisation that is an inspiring place to work, innovative and improving public and patient health. Painting a compelling vision of the future was identified as a critical action required from the Gate 0 review programme too.

3.3. The Gate 0 independent review made 7 recommendations and the committee was encouraged that these are being progressed. The Director of Delivery is developing a delivery team that will work closely with the service owners across the Agency.

3.4. It was noted that RMS is a big enabler of change, as is the filling of vacancies. It was noted that high workloads have been a barrier to making progress to change and improve the delivery of services.

3.5. It was recognised that change can be very difficult but some simple tools like "The 5 Whys" or simple "Value Stream Mapping" can help to identify activities that do not add value and could in turn reduce workload.

3.6. Creating an environment where staff feel confident to question the status quo and take risk-based decisions supported by their managers in an open and transparent way will be important for the success of the programme.

3.7. There has been good progress on designing and improving the regulation of established medicines which can be a pilot for other areas across the organisation.

3.8. Given the defined timeline for the RMS programme, this can act as a focus to improve processes and deliver change. It can act as a catalyst for doing things differently and as a way of creating a climate of continuous improvement and risk-based decision-making.

4. Update on progress of the RMS Minimum Viable Product (MVP)

4.1. The MHRA's Chief Healthcare Quality & Access Officer, the SRO for the RMS programme, outlined the progress that has been made and on defining the scope and delivery planning of the MVP. There has been good progress since the last update made to the joint meeting with the Audit & Risk Assurance Committee in September.

4.2. There is a hard cut-off date for delivery of the MVP of March 2024 when Lotus Notes will be shut down.

4.3. It was agreed that the MVP should deliver the end-to-end scope rather than a pilot programme. The earliest feasible date to do this will be November 2023 and include the core platform build.

4.4. This is a highly complicated programme of work that is fundamental to delivering the Agency's strategic objectives. Communication of progress of RMS and the service transformation programme is an opportunity to inspire and motivate staff to address many of the concerns that they have expressed. Telling success stories and how collaboration is helping address and reduce workload.

4.5. Whilst RMS is a more complex programme, there are some key areas of learning from the delivery of the SafetyConnect programme.

4.6. There are significant risks with the programme; financial, technical and delivery. A phased delivery programme is being developed. Risks will be managed through the programme governance structure and monitored through the Agency risk register.

5. ODRC Effectiveness Review

5.1. The survey of Board Members had indicated that the ODRC could make improvements in giving assurance to the board on the effectiveness of transformation.

5.2. The current ODRC Terms of Reference will be updated to include assurance on transformation and organisational effectiveness.

5.3. The composition of the committee will also be reviewed to ensure that membership reflects the changed scope. It was proposed that a Chief Officer and the Director of Delivery become full time members.

5.4. The chair is speaking to Chief Officers to get specific feedback on the committee and will collate and feedback to the next committee

6. Concluding Remarks

6.1. The Agency has reached a critical stage in its Transformation Programme and the progress made in 2023 will be critical to laying the foundations to deliver its strategic goals outlined in the Corporate Plan.

6.2. Progress is now being made on filling key vacancies across all the different areas. This in time will reduce the workload on individuals who have been covering multiple roles and ensure that there is time to focus on designing and delivering new ways of working and services to meet future needs of patients and public health.

6.3. A comprehensive programme of work has been developed to improve employee satisfaction and staff motivation. It was recognised that the most powerful impact is made by local managers working closely with their teams and this has been made much more difficult by the high vacancy levels and lack of clarity on the end state of the Transformation Programme.

6.4. The Gate 0 Review identified the urgent need to agree, articulate and share a clear visionary end-state for the Transformation Programme. The committee fully supported this and emphasised the importance of communication that relates to the needs of staff. Outlining “what the change means for me”, using inspiring stories, encouraging wide participation and acknowledging areas for improvement.

6.5. The committee welcomed the appointment of the Director of Delivery as the SRO for Transformation. This is a key role and it was encouraged that his team are being recruited to support the new ways of working across the Agency.

6.6. The services work is making good progress in Established Medicines and this will be a pilot for roll-out to other services and teams going forward.

6.7. The RMS is planned to deliver an end-to-end MVP by November 2023 and it was noted that the deadline for delivery is March 2024 when Lotus Notes will be shut down. Governance and Risk Management processes are in place for the programme.

6.8. The committee reviewed its own effectiveness and has proposed changes to its Terms of Reference and membership.

Amanda Calvert
Chair of Organisational Development & Remuneration Committee
January 2023

Medicines & Healthcare products Regulatory Agency

BOARD MEETING HELD IN PUBLIC

17 January 2023

Title	**What assurance can be provided by the Patient Safety & Engagement Committee?**
Board Sponsor	Mercy Jeyasingham
Purpose of Paper	Assurance

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

1. Executive Summary

1.1 The Patient Safety & Engagement Committee (PSEC) discussed two main areas at its meeting on the 16th of December 2022. However, it also conducted business via email to sign off the one year update on the Patient Involvement Strategy to ensure its timely publication in November. The two main areas discussed in the meeting were the publishing of safety "signals" and the use of risk benefit workshops to inform communications with the public and health professionals.

2. Introduction

2.1 The ninth meeting of the PSEC was held on the 16th of December 2022.

3. PSEC discussed each of the following items at the meeting on the 16th of December 2022;

3.1 Should we publish "signals" to better inform the public and healthcare professionals of potential safety concerns? If so, how?

The MHRA publishes data on suspected Adverse Drug Reactions to medicines on the Yellow Card website. The visibility of this information was being enhanced on the website during December. The Committee discussed a strategy to further improve transparency by publishing data from signals identified through routine signal detection activities. Some of the issues considered were raising public concerns when evidence of risk was at an early stage and might not be linked to the medicine under consideration; how to communicate clearly on the evidence so far and what that could mean; at what stage to publish the data; when to include signals on devices; and the impact on resource in terms of time and people this would take. The Committee looked at other regulators, especially the EU and the FDA is the USA. PSEC concluded that transparency was the right direction of travel. A pilot that considers signals related to medicines taken to the Pharmacovigilance Expert Advisory Group will be devised and closely monitored. Results will be brought back to PSEC.

3.2 How will we use workshops on risk benefit communications to inform our future approach to communicating with the public and health care professionals?

In the last year more work has been focused on the communication of risk. In particular the Agency has made contact with several academic institutions. The Committee were asked to consider the development of a new risk communications strategy. A Health Care Professionals consultation on risk and safety communications is currently live. Results from the consultation as well as workshops and interviews with health and care professionals and patients will inform a risk benefit communication strategy and the development of the Agency's communication and engagement tools in relation to risk. The Committee

considered the use of media, how ethics would inform the strategy, and how this work related to the previous topic of discussion, the communication of safety signals. The Committee discussed the development of the strategy and agreed the approach.

3.3 **Actions arising and review of previous topics**

An action arising included an agreed forward plan of Committee topics. This is being co-ordinated with Board agendas and will be presented at the next PSEC. A timetable of when topics discussed at Committee are reviewed will form part of this forward plan.

4. Conclusion

4.1 The main topics discussed at the Committee complemented each other as there were a number of similar issues relevant to both papers. The Committee noted the move to greater transparency in decision making and communication of risk. The work with academic institutions was welcomed as the use and expansion of evidence in communication of risk is a key interest of the Agency.

Mercy Jeyasingham
Chair of Patient Safety & Engagement Committee
December 2022

Medicines & Healthcare products Regulatory Agency

BOARD MEETING HELD IN PUBLIC

17 January 2023

Title	**How will the Assurance and Governance Framework of the MHRA continue to be improved?**
Board Sponsor	Carly McGurry
Purpose of Paper	Approval

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

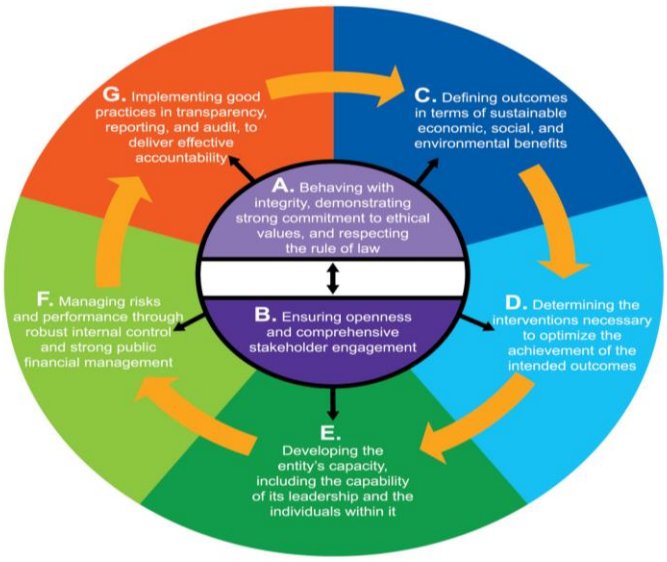
1. Executive Summary

1.1 This paper proposes the most critical risks to the achievement of the Agency's strategic objectives for discussion and review. These have been identified through discussion with Chief Officers and staff across the organisation and from the outputs of the Audit and Risk Assurance Committee (ARAC) horizon scanning risk meeting held in September 2022. The Board is asked to consider whether these represent the Agency's most critical risks or whether anything is missing. The Board is also asked for views on how we ensure the identified risks are mitigated throughout the Agency, beyond the prescribed Government risk management process.

2. Introduction

2.1 The Agency's Governance and Assurance Framework (the Framework) is concerned with the processes and ways of working that enable the organisation to succeed. The Framework is informed by a number of external requirements and pulls together a range of elements which should enable the Agency to identify and articulate its strategy and objectives to be delivered, to monitor performance, to manage risks to the delivery of those objectives and provide assurance that risks are appropriately managed and objectives are achievable. Elements of our Framework include our underpinning legislative duties, our Framework Agreement with DHSC, central government requirements such as Managing Public Money and other guidance, as well as our Delivery Plan, our performance management systems, decision making systems and terms of reference for key governance forums, financial authority rules and pan-Agency policies and procedures, such as on conflicts of interest, or speaking up. In assessing and continuing to improve our Framework, we are using the CIPFA/IFAC international framework as set out in the model below[1].

[1] International Framework Good Governance in the Public Sector | CIPFA



2.2 Over recent years, the Agency has chosen to put greater investment into its governance arrangements to maximise the likelihood of success of the organisation and to better manage risks to realising that success. Effective governance arrangements are also critical to complying with the expectations of a public body and commanding the confidence of the public in how we transparently discharge our duties and utilise the resources at our disposal. Board members may remember that the Agency commenced planning for the Transformation Programme on the back of an external governance review in 2020, which concluded that there was scope for a range of improvements, including greater clarity on roles, responsibilities and decision-making processes and more effective performance management.

2.3 In response, and as part of the Transformation Programme, the Agency created the Governance Office, bringing together a range of previously disparate functions and providing a clear point of focus for effective governance, operating in close partnership with an array of colleagues, such as with Finance on corporate, business planning and performance management, HR teams, as well as information assurance and legal colleagues. In conjunction with those colleagues, a range of work has been undertaken to embed ongoing improvements to our Framework. This work is set out below, arranged by work completed, work underway and priorities for the coming year.

3. Improvements completed

3.1 Over the last twelve months, we have collectively delivered a range of improvements to the Framework, as summarised briefly below:

- Improved **support for the operation of the Agency Board** and its committees, via improved planning and scheduling, early commissioning of papers and improved clarity on the purpose of agenda items. This also included support for Board reflection on its own effectiveness and support for external review and development.

- Redevelopment of the Board **conflict of interest** policy, supporting colleagues to ensure compliance and revitalising our approach to sharing timely information on any potential conflicts and their mitigations; development of, consultation on and launch of a new code of conduct for conflict of interests in members of advisory bodies, bringing the various bodies into line with one another where activities are similar and to reflect best practice; relaunch of the internal governance group to identify and mitigate any corporate conflicts of interest, with new members and processes across the organisation and information on any such conflicts published on the Agency's website.

- Working with colleagues in DHSC, a wholesale review of the Agency's **Framework Agreement** with the department, setting out the roles, responsibilities and accountabilities of both parties. This has addressed a range of outdated requirements and brought the Agreement in line with best practice as set out by the Cabinet Office and HM Treasury. It has also provided a timely opportunity to set a new vision with our sponsor team in DHSC on how a mature partnership operates in practice, to best enable mutual success. In turn, this has allowed us to consolidate and build upon our existing approaches to our formal **Quarterly Accountability Meetings** with DHSC sponsors, to deliver a greater focus on critical aspects of performance and key issues for resolution.

- The completion of the **annual report** has moved to the Governance Office to own and coordinate, with input from across the Agency and ongoing ownership of the financial audit and accounts by Finance. Lessons have been identified from this first year and built into the approach for the coming year, but there was a general acknowledgement that our collective approach was growing in strength as a result of the new arrangements.

- Respective areas have been developing their alignment with the government's **functional standards** independently, with property, commercial and whistleblowing well advanced and our fraud detection activities subject to external assurance by the DHSC fraud team.

- The new arrangements for reviewing, agreeing and monitoring our **policies and procedures** has been established under the auspices of the Risk and Audit Group (Executive) to ensure a consistent approach to updating or creating policies and procedures across the Agency and that staff will recognise a corporate approach across the piece.

- We have maintained our improved approach to **risk management** throughout the year, with a horizon scanning discussion with members of ARAC in September and discussion at the Executive Committee (ExCo) throughout the year. However, with a gap in expertise and delay in bringing new staff into the organisation, we have not been able to push ahead with a range of improvements on risk management as quickly as we would have wanted.

4. Improvements underway

4.1 With the above work completed, we have also begun to work to deliver additional significant improvements to the Framework. Unlike the above, this additional work is likely to take longer to complete given its complexity and impact across the organisation. This work includes:

- Review and refresh of the **operation of ExCo and its supporting management committees**. This work kicked off in earnest over the late summer, with an informal review of reserved matters for ExCo and the standing items it wished to consider on a regular basis. This is the starting point for improving the understanding and definitions of authority delegated to other decision-making bodies, to help increase our speed and agility in ensuring decisions are taken at the right level at the right time with the right information. ExCo have discussed and agreed to a range of changes in how the management committees are running, particularly in relation to chairing and membership. Existing arrangements designed to ensure transparency, visibility and a virtuous cycle of feedback across the executive governance structure will be tightened up and enforced. With chairs now agreed for five of the six management committees, work is underway to support the transition, confirming membership across the senior leadership cadre and reviewing terms of reference and forward work programmes. Support and monitoring will continue as the committees bed in to their new ways of working to ensure we maximise the anticipated benefits from this refresh.

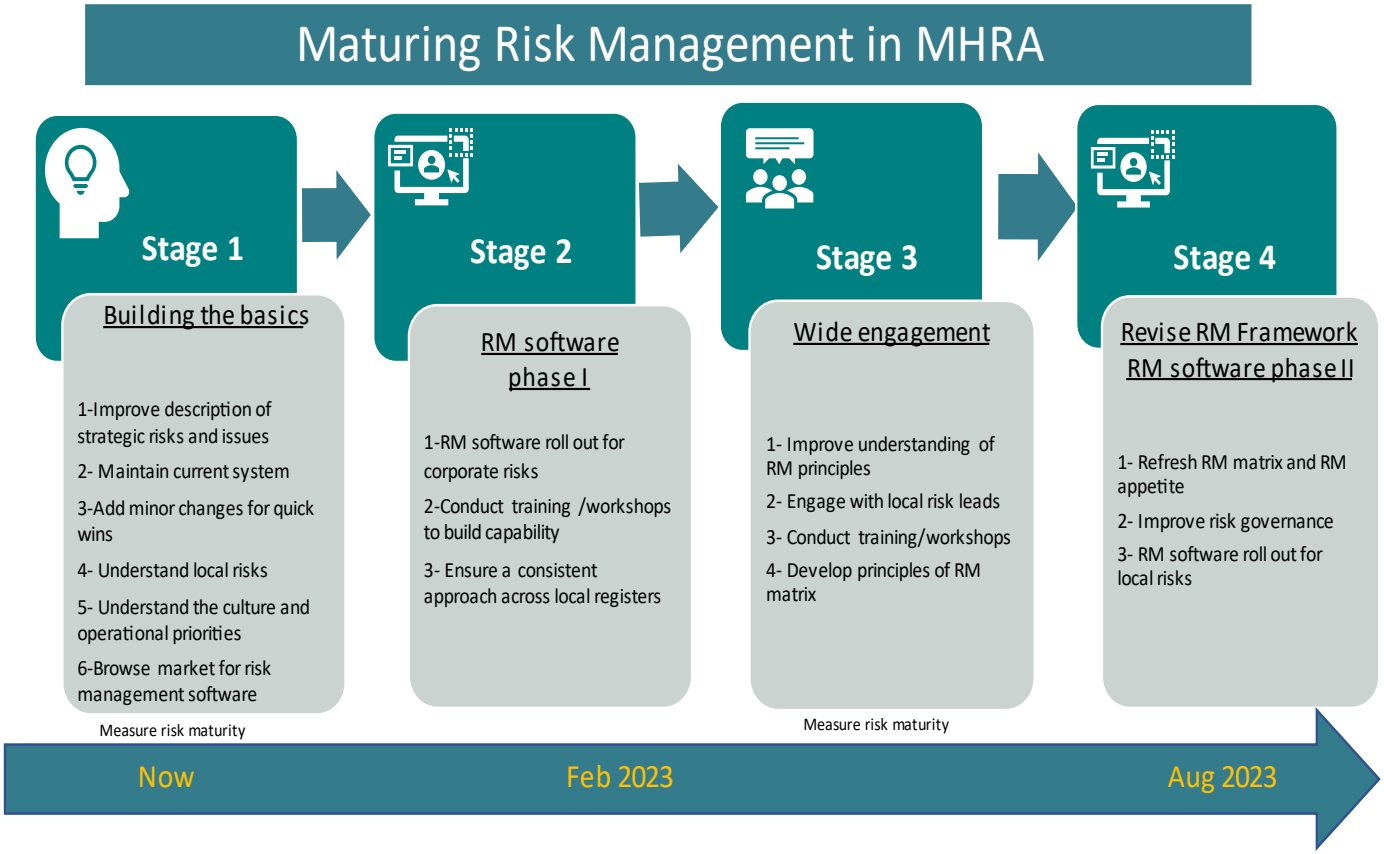
- Refreshed management committees will be further complemented by the ongoing development of our **One Agency Leadership Group**. Operating at the senior leadership level, this group is bringing leaders together via a self-directed remit to add greater vigour, input and ownership to the ongoing leadership of the Agency, ranging across topics such as the development of content for the new corporate plan to agreeing specific actions to be delivered by group members on the people, cultural and social aspects of the Agency's development.

- Development of a **pan-Agency schedule of delegated authority**. This is key area for the Framework and one that is recognised as a current gap – an audit of the corporate governance arrangements in May of this year gave an opinion of moderate assurance overall, with one high priority recommendation focused on the need for an Agency-wide scheme of delegation. This is a complex area and we have had significant input from operational areas so far as we seek to develop this from our base legislative powers outwards. We aim to have an outline framework for the schedule to discuss with ExCo early in the new year, which will then likely require further development. This schedule will sit at the corporate leadership level, and we will then work with individual groups to support them as they develop underpinning local schedules relevant to their individual activities. We anticipate that there will be further work arising on the back of the development of the corporate and local

schedules, such as changes to working practices and standard operating procedures. We are ensuring that this work is in line with and responding to the services redevelopment underway. The outcome of the creation of this schedule will be to further support staff across the Agency to understand where decisions are taken and the accountability for those, providing the parameters to work at pace but with appropriate controls in place.

- Alongside the schedule, we are working to **improve the production and use of management information** across the Agency. This involves bringing together sets of information that exist and or are being actively provided to Groups which set out performance across a range of indicators, such as income, expenditure, staff turnover, sickness absence, use of reward schemes, complaints and correspondence levels to name just a few. This will be brought together with appropriate performance metrics for each group and will determine the consistent approach to be taken across all groups to considering and acting upon this information, in line with delegated authority, to improve monitoring and management across the whole Agency. This work, when completed, will support and feed into the Agency's **Balanced Scorecard**. Effective performance management is a critical component of our Framework as set out in 2.1 above, but as the Board is very familiar with the ongoing development of and improvements to the Balanced Scorecard, we have not included further detail in this paper.

- With new capacity and capability now embedded in the team, the diagram below sets out the plan to **further improve the maturity of risk management** in the coming months to ensure we have a robust grip on our key strategic risks, our controls and mitigations. This is carefully planned through a number of stages to allow for maximum engagement across the Agency as we further develop this function.



- Arranging the steps required to deliver an improved overall **risk framework** in this manner allows the risk management function to work with staff across the Agency to build both greater understanding and a more accurate, Agency specific risk framework and appetite for the future. Ultimately it is the engagement with and operation of risk management right across the Agency that will improve our outcomes in this area, both in managing ongoing strategic risks and blockers and in recognising opportunities and adequately managing the risks that inevitably arise from embracing those opportunities. While the Framework itself will continue to improve and evolve, beyond the timeframe set out here, its ultimate success rests upon equipping staff at all levels with appropriate knowledge and developing a culture or 'way of doing business' that puts this knowledge to effective use.

5. Priorities for the coming year

5.1 As the Board is aware, the whole Agency has gone through a substantial change in structure in this phase of the Transformation Programme and endured significant gaps in staffing in some areas. This has created additional challenge in introducing new systems and frameworks and accurately understanding requirements arising from new structures. The Governance Office is now approaching full staff complement with additional expertise brought into the specific functions where necessary. With staff vacancies slowly reducing across the Agency, we anticipate that the coming year should provide greater

opportunity to build the relationships and knowledge that is a pre-requisite for successful implementation of ongoing improvements to the Agency's governance and assurance Framework. With that in mind, key objectives for the coming year include:

- Finalising the schedule of delegated authority and supporting every area of the organisation to develop local schedules
- Supporting the development of the corporate and business plans, incorporating meaningful performance monitoring from the outset
- Completing a self-assessment against all of the government's 13 functional standards (with the exception of the Finance function who are moving straight to external assurance) and developing a targeted programme of further assurance in partnership with internal audit colleagues
- Development of our pan-Agency risk maturity as described above
- Development of a code of conduct for staff, as now required by the draft updated Framework Agreement with DHSC, bringing together expectations and guidance in one place to support staff in complying with their obligations
- Developing a more sophisticated process for completing an annual review of our Governance and Assurance Framework ahead of production of the Governance Statement in the annual report, to embed a culture of continuous improvement and best practice, working with a range of internal and external partners.

5.2 Governance Office, working with colleagues, including those referenced in this paper, can drive forward much of the delivery in this space, in the form of structures, systems and processes. However, successful governance relies not only on those 'hard' elements, but also on 'soft' elements: the culture of the organisation in embracing and prioritising governance and assurance as a way of doing business rather than being considered a bureaucratic overhead or box ticking exercise; the continual embedding of governance and assurance into everyday life; the tone of the leadership cadre in setting out the value of our governance to underpin and support our delivery. Governance Office will work to ensure that the ongoing improvements to our Framework are reflected in people and culture activities, threaded throughout our corporate and business plans and promoted to staff. However, it will be for the whole of the leadership cadre to work together to ensure success, both in our governance and for the organisation as a whole.

Carly McGurry
January 2023