Medicines & Healthcare products Regulatory Agency

AGENDA FOR BOARD MEETING HELD IN PUBLIC

10:00 – 12:15 on Tuesday 15 February 2022

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
10:15	AGENCY PERFORMANCE 4. What are our most important activities and priorities from the CEO's point of view?	Context	June Raine
10:35	5. How much of the Delivery Plan have we achieved from April to December 2021?	Assurance	Jon Fundrey
10:55	DYNAMIC ORGANISATION 6. How are we performing on Health and Safety compared to best practice?	Assurance	Marc Bailey
11:15	7. What assurance can be provided by the Organisational Development and Remuneration Committee?	Assurance	Amanda Calvert
11:30	FINANCIAL SUSTAINABILITY 8. What assurance can be provided by the Audit & Risk Assurance Committee?	Assurance	Michael Whitehouse
11:45	EXTERNAL PERSPECTIVE 9. What questions do members of the public have for the Board?	Public Engagement	Chair
12:15	CLOSE OF MEETING	-	Chair

MHRA Agency Board Declarations of Interest – February 2022

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 Designate	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
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.	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
Dr Alison Cave Chief Safety Officer	None	N/A	N/A	N/A
Jon Fundrey Chief Operating Officer	None	N/A	N/A	N/A

Name and MHRA Role	Name of Other Company or Organisation	Nature of interest	Paid	Current
Dr Paul Goldsmith Non-Executive Director	Closed Loop Medicine Ltd	Shareholder, director & employee	Yes	Yes
	Summit Inc	Shareholder	No	Yes
	Ieso Digital Health	Shareholder	No	Yes
	MDU Ltd	Director	Yes	Yes
	MDU Investments Ltd	Director	Yes	Yes
	NHS	Consultant Neurologist	Yes	Yes
	NHS	Clinical Senate Member	No	Yes
	Big Tent Foundation	Trustee	No	Yes
	Radix Group Limited	Trustee	No	Yes
	Sleepstation	Co-founder of original programme, 2012-2014	No	No
Professor Graham Cooke Non-Executive Director and Deputy Chair	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	Yes
	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
	NIHR	NIHR Research Professor	Yes	Yes
Claire Harrison Chief Technology Officer	None	N/A	N/A	N/A
Haider Husain Associate 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 Ward Muslim Memorial Trust	Trustee	No	Yes
	Microsoft Corp	Shareholder	Yes	Yes
	BBC	Family Member	No	Yes
Mercy Jeyasingham MBE Non-Executive Director	Royal College of Podiatry	Consultancy	Yes	No

Name and MHRA Role	Name of Other Company or Organisation	Nature of interest	Paid	Current
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	Yes
	PAVIA – PV Africa Board (EC Funded)	Advisory Board	No	Yes
	WHO – Sustainable COVAX Manufacturing Strategy for Regional Health Security	Advisory Expert	No	Yes
Laura Squire OBE Chief Healthcare Quality & Access Officer	None	N/A	N/A	N/A
Michael Whitehouse OBE Non-Executive Director	South East Coast Ambulance Services NHS Foundation Trust	Deputy Chair & Senior Independent Non-Executive Director Chair of Audit Committee Chair of Charities Committee	Yes	Yes
	Cruse Bereavement Charity	Trustee Chair of Finance and Audit Committee	No	Yes
	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 of 18 January 2022

(10:00am – 12:30pm)

by Zoom Webinar

Present:

The Board

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

Others in attendance

Rachel Bosworth	Director of Communications, MHRA
Natalie Richards	Head of the Executive Office, MHRA
Johan Ordish	Group Manager, Medical Device Software and Digital Health, MHRA
Kathryn Glover	Deputy Director, Medicines Regulation and Prescribing, DHSC
Greig Chalmers	Head of Chief Medical Officer's Policy Division, Scottish Government

INTRODUCTION

Item 1: What are the priorities for this meeting, how will the meeting run 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.

1.2 The Chair welcomed everyone to the meeting, including a broad range of observers representing patient groups, healthcare professionals, government, industry, media and MHRA staff.

1.3 The Chair also welcomed Dr Glenn Wells who joined the MHRA as Chief Partnerships Officer in December 2021.

1.4 The Chair congratulated Dame June Raine on being made a Dame Commander of The Most Excellent Order of the British Empire (DBE) for Services to Healthcare and the Covid-19 Response in the 2022 New Year's Honours list, which reflects Dame June's personal contribution and the incredible work the MHRA has done in response to the COVID-19 pandemic.

Item 2: Are there any Apologies or Declarations of Interest

2.1 Apologies were received from Alison Strath, Interim Chief Pharmaceutical Officer and Deputy Director at the Scottish Government, Cathy Harrison, Chief Pharmaceutical Officer for Northern Ireland, and Carly McGurry, Director of Governance.

2.2 The Board reviewed the Declarations of Interest for all MHRA Board members. Claire Harrison confirmed that she has no Declarations of Interest and the Board agreed this list as an accurate record.

2.3 The Board noted that there is a paper on Artificial Intelligence (AI) as a Medical Device on the agenda of this meeting. The Board also noted the Declarations of Interest that Haider Husain is a member of a BSI Panel establishing standards on the use of AI within healthcare, and Junaid Bajwa is the Chief Medical Scientist at Microsoft Research, which is developing AI for a number of applications including healthcare. The Chair confirmed that as the Board will be asked to comment on the strategic direction for the regulation of AI as a Medical Device at this meeting and will not be asked to make any specific regulatory decisions, he was satisfied that Haider and Junaid could continue to participate in this agenda item on this occasion.

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. The Board noted the progress update on the Communications Strategy, action 39, and agreed the impact of this should be measured in the Balanced Scorecard.

AGENCY PERFORMANCE

Item 4: What are the current issues from the CEO's point of view?

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

(i) Healthcare Access – including latest updates on COVID-19 antivirals; COVID-19 vaccines, including the one-year anniversary of approving the first COVID-19 vaccine; the Innovative Licensing & Access Pathway (ILAP); clinical trials legislation and process; innovation in clinical trials supported by the Clinical Practice Research Datalink (CPRD); use of real-world data for clinical trials; innovative devices; best practice guidance for Advanced Therapy Medicinal Products; and neurovirulence of Polio vaccine;

(ii) Patient Safety – including updates on the safety of COVID-19 vaccines; antiviral safety surveillance; the safety review of Isotretinoin; medicine recalls; and enforcement activities;

(iii) Partnerships – including updates on the Access Consortium; international collaboration on remote inspections; and scientific speaking and training engagements;

(iv) Dynamic Organisation – including updates on the Transformation Programme; the Applications Outsourcing Transition; and external audits; and

(v) Financial Sustainability – including updates on accommodation; and the transition from Trading Fund status.

4.2 The Board thanked Dr Raine for her report and provided comments on using the leverage of CPRD in the primary and secondary care data space to further develop the use of Real World Evidence (RWE); use of RWE to review variants; how to move towards a better connected health system; the uniqueness of the health system and regulatory regime in the UK and how to build on this; the accommodation strategy and implications for the Agency's operations, noting the Agency will reduce its footprint in 10 South Colonnade offices; and how to facilitate development of clinical trials to enable greater patient recruitment. The feedback from the ongoing public consultation on clinical trial regulations will be reviewed, and strategic recommendations will be made on areas for development. An action was taken to develop and present a Data Strategy to the Board for strategic direction.

Further addition to action 61: Review feedback from public consultation on clinical trial regulations and make strategic recommendations on areas for development
Marc Bailey

Action 70: Develop and present a Data Strategy to the Board.
Alison Cave & Claire Harrison

Item 5: What is performance of the MHRA on the Balanced Scorecard in Month 8?

5.1 The Board discussed the current performance of the MHRA, presented via the Balanced Scorecard. The Board considered whether the metrics and the commentary provided appropriate assurance that current performance is on track and aligned to the Agency's strategic objectives. The Board commented that at present the Balanced Scorecard continues to focus on inward-looking operational volume metrics rather than strategic outcome measures.

5.2 Chief Officers proposed the type of metrics which would be required to give the Board assurance that the current performance of the Agency is on track and aligned to strategic objectives. In the area of Science Research & Innovation, at present only clinical trial applications and biological standard sales are presented, but there are no trends to the data, there is no reference to strategic goals and there is a lack of context. The short, medium and long-term impact of the scientific activities the Agency is undertaking needs to be presented.

5.3 In the area of Healthcare Quality & Access, information is required on the time taken for innovative, new and established products to be approved so that the NHS and patients can access them. Some focus is also required on our delivery against the Life Science Vision priorities.

5.4 In the area of Safety & Surveillance, there is also a need to move from input to outputs. More meaningful information on signal detection, level of risk, regulatory action and impact on outcomes should be included. There should also be better reporting on the impact of CPRD and the outcome of our enforcement activities.

5.5 The Board noted the proposals for improved metrics within the Balanced Scorecard and provide comments regarding the development of innovation measures which demonstrate impact; development of patient involvement measures linked to the Cumberlege deliverables; the importance of developing a reputation index; the development of streamlined processes and the inclusion of the time taken in the measures; and the impact of partnership-working.

5.6 The Board provided further comments on building our international aspirations into the Balanced Scorecard by undertaking benchmarking of the Agency's activities against other world-class regulatory agencies; and how to develop a culture of feedback and continuous improvement. The Board agreed that it is now time to renew our thinking on how best to use the Balanced Scorecard. An action was taken to develop a new approach for Board Reporting focused on operational performance, risk management and opportunity progression. This should be presented to the Board in March 2021.

Further addition to action 51: A new approach for Board Reporting on operational performance, risk management and opportunity progression to be recommended to the Board. ***Jon Fundrey***

PATIENT SAFETY

Item 6: How will the outcomes and short, medium and long-term benefits arising from activities being undertaken to address the recommendations of the Cumberlege Review be measured?

6.1 The Board considered a report describing how the MHRA proposes to better measure the impact of the activities we are implementing as a direct result of the Cumberlege Report's findings and recommendations. The Board specifically reviewed the benefit maps which consolidate the key activities across the Agency in response to Recommendation 6 of the Cumberlege Review, and how these activities are mapped with deliverables, indicators and potential outcomes in order to track progress against anticipated longer-term benefits.

6.2 The Board provided comments regarding the need to iterate these measures to ensure delivery of the benefits; utilising the Patient Safety & Engagement Committee (PSEC) to develop new ideas and undertake more in-depth interpretation to provide assurance to the Board; how to ensure representativeness of the Patient Group Consultative Forum; how to ensure the work in this area can translate in to changes to the regulatory framework; and the recruitment of the Patient Safety Commissioner.

6.3 The Board provided further comments regarding how the benefits maps describe an Agency-wide picture of activities and ensure the Board understands the risks related to resource. The development of some case studies of known patient safety issues and the risk mitigation measures taken would help to bring this to life. An action was also taken to conduct a review of the cross-agency actions that have delivered a meaningful and positive difference to patient safety and risk management in the two years since the Cumberlege Review was published.

Further addition to action 52: The Board requested a review of the cross-agency actions that have delivered a meaningful and positive difference to patient safety and risk management in the two years since the Cumberlege Review was published.
Alison Cave

Item 7: What assurance can be provided by the Patient Safety & Engagement Committee?

7.1 The Board considered the assurance report from the PSEC, which had reviewed the public consultation on the medical devices' legislation; the outcomes and progress from the Independent Medicines and Medical Devices Safety Review (Cumberlege Review); the isotretinoin review; feedback on recent meetings with NICE and Health Technology Wales; and the committee's revised Terms of Reference. The Board was content with the assurance provided from the PSEC.

Item 8: What are the updated Terms of Reference for the Patient Safety & Engagement Committee?

8.1 The Board reviewed the updated Terms of Reference for the PSEC, noting that the limited number of amendments aimed to clarify the responsibilities of the Committee, add a lay representative to the quorum and ensure flexibility of conducting meetings outside the scheduled quarterly meetings. The Board approved the proposed PSEC Terms of Reference.

HEALTHCARE ACCESS

Item 9: What are the strategic priorities for the regulation of Artificial Intelligence as a Medical Device and how can this be developed effectively?

9.1 The Board considered a paper describing the strategic priorities for the regulation of Artificial Intelligence as a Medical Device (AIaMD); the key benefits as well as challenges that AIaMD can pose over and above other software; the principles and pillars that underpin the MHRA's AIaMD reform programme; a summary indication of what gaps were identified that the programme intends to fill; broad details of the three work packages for AIaMD; and an indication of how these work packages will be delivered.

9.2 The Board provided comments regarding the importance of partnering with other regulators in the UK health system; the importance of providing examples of where the MHRA has approved products which are classed as AI – such as AI readers for COVID-19 lateral flow test results; ensuring minimisation of unintended bias; and ensuring AIaMD is included within the cross-Agency Data Strategy.

9.3 The Board provided further comments relating to the safety and reliability of AI models; responsible and ethical AI; data transparency and privacy; inclusivity and ensuring the limitations of AI are taken into account; greater communication with the NHS, clinicians and industry; understanding unintended consequences on the use of AI; the use of synthetic data as a test bed; and using the priorities in the Life Sciences Vision to focus on areas for development where this technology can make a difference. It is important that the primary focus of this work is to deliver for patients. The Agency should take the opportunity to publish the results of this work. The Board supported the strategic priorities laid out in this paper.

Action 71: 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***

EXTERNAL PERSPECTIVE

Item 10: What questions do members of the public have for the MHRA Board?

9.1 The Board answered a range of questions from members of the public. A large number of questions were submitted by members of the public before and during the meeting. Although most of these questions were answered, it was not possible to address them all in the available time. An action was taken to answer all remaining questions in writing to the people who raised them.

Action 72: Send written responses to observers whose questions were not answered during the January Board Meeting ***June Raine***

ANY OTHER BUSINESS

10.1 No additional business was raised and the Chair closed the meeting with thanks to all of the contributors and members of the public observing the meeting.

ACTIONS FROM MHRA BOARD MEETING IN PUBLIC – 18 January 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 Laboratory Strategy to the Board as part of the Agency Science Strategy.	Marc Bailey	~~21/09/21~~ ~~16/11/21~~ ~~15/03/22~~ 17/05/22	
34	20/4/21: The MHRA had a commitment in the Life Sciences Sector Deal 2 to publish a new regulatory pathway for genomic medicines and genomic tests by March 2021. Provide an update on progress of this commitment. 21/09/21: Publish communication on GOV.UK on the MHRA work to develop a pathway for new genomic products	June Raine	~~18/05/21~~ ~~21/09/21~~ ~~19/10/21~~ ~~16/11/21~~ 18/01/22	Completed
38	18/05/21: PSEC and ARAC to agree how to provide assurance to the Board on the development, governance and data standards of SafetyConnect	Mercy Jeyasingham & Michael Whitehouse	~~20/07/21~~ 15/03/22	
39	18/05/21: Implement the approved Communications Strategy with particular focus on measuring trust &communication with HCPs	Rachel Bosworth	~~16/11/21~~ 18/01/22	Progress update provided. This action can be closed and impact will be measured in the Balanced Scorecard.
43	15/06/21: A revised assurance and governance framework for the new MHRA organisation should be presented to the Board.	Carly McGurry	~~15/02/22~~ 17/05/22	
46	15/06/21: The Board's comments on the future development &branding of ILAP, including its potential use for medical devices, should be considered so that a definitive proposal can be presented to the Board for approval. 16/11/21: Consider if ILAP should be rebranded as an "Innovative Therapy Pathway" and conduct a pilot with a medical device through this innovative regulatory route.	Laura Squire	~~19/10/21~~ ~~16/11/21~~ 19/04/22	

51	20/07/21: Review Balanced Scorecard metrics and targets to provide more focus on outcomes, greater links to the Delivery Plan and (especially on innovation) and assurance that resources are available to deliver priorities 21/09/21: Review the outcome measures in the Balanced Scorecard and the RAG Ratings in the quarterly Delivery Plan reports before considering if the targets are ambitious enough. 19/10/21: Continue to evolve the Balanced Scorecard metrics to include more outcome measures. Update the data set for Clinical Trials in the balanced scorecard. 16/11/21: Broaden the measures to include the impact and quality of our scientific work rather than volumes. Seek input from our customers on what MHRA services they value for inclusion in the Balanced Scorecard. 18/01/22: A new approach for Board Reporting on operational performance, risk management and opportunity progression to be recommended to the Board.	Jon Fundrey	~~19/10/21~~ ~~16/11/21~~ ~~18/01/22~~ 15/03/11	
52	20/07/21: Review how multiple data sources including Unique Device Identifiers, Registries, NHS data and real world data can be captured and used to strengthen safety surveillance. Incorporate this into the planned review of SafetyConnect 18/01/22: The Board requested a review of the cross-agency actions that have delivered a meaningful and positive difference to patient safety and risk management in the two years since the Cumberlege Review was published.	Alison Cave	~~16/11/21~~ ~~18/01/22~~ 17/05/22	

54	20/07/21: Review the progress and impact of the short, medium and long term deliverables of the agreed Culture, Equality, Diversity and Inclusion plans	Jon Fundrey	~~18/01/22~~ ~~15/02/22~~ 17/05/22	On Agenda
58	21/09/21: Update MHRA/DHSC Framework Agreement to coincide with the change in Trading Fund status.	Carly McGurry	31/03/22	
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	
61	19/10/21: Prioritise the national and international initiatives to accelerate the diversification of patient recruitment for clinical trials, exploring options to maintain diversification of representation (eg gender balance). Consider development of a public dashboard of metrics for trial recruitment. 18/01/22: Review feedback from public consultation on clinical trial regulations and make strategic recommendations on areas for development	Marc Bailey	~~19/04/22~~ 19/07/22	
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	
64	16/11/21: Review opportunities for more partnership working with other regulators as part of the MHRA International Strategy	Glenn Wells	~~15/02/22~~ 19/04/22	
65	16/11/21: PSEC to seek assurance on how safety risks are considered by the MHRA in those situations where patients are willing to accept more risk than healthcare professionals.	Mercy Jeyasingham	19/04/22	
66	16/11/21: Assurance to be provided to ODRC on actions being taken to improve culture survey scores (ie walking the talk and taking timely decisions) in the Balanced Scorecard	Executive Committee	15/02/22	On Agenda

67	16/11/21: Update the RAG rating on the use of financial reserves in the Delivery Plan	Jon Fundrey	15/02/22	On Agenda
68	Meet with the Mesh UK patient group to discuss rectopexy mesh and hernia mesh complications	Alison Cave	15/02/22	Completed
69	Send written responses to observers whose questions were not answered during the November Board Meeting.	June Raine	18/01/22	Completed
New Actions				
70	18/01/22: Develop and present a Data Strategy to the Board	Alison Cave & Claire Harrison	17/05/22	
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	
72	18/01/22: Send written responses to observers whose questions were not answered during January Board Meeting	June Raine	15/02/22	

Medicines & Healthcare products Regulatory Agency

BOARD MEETING HELD IN PUBLIC

15 February 2022

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

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

'TOP 10' HEADLINES

- Transformation to the new One Agency structure was launched on 10 January, establishing our One Agency Leadership Group and recruiting to fill the new roles.
- Innovative Licensing and Access Pathway (ILAP) 'Summit' Meeting was held with key stakeholders including patient groups to review progress and plan future work.
- Guidance on genomic medicines was published on ILAP webpage and work is under way on an innovative pathway for medical devices for unmet medical need.
- MHRA contributed to the government strategy to realise the Benefits of Brexit in relation to 1) Medical Devices including Artificial Intelligence, and 2) Clinical Trials.
- Public consultation started on clinical trials legislation to streamline approvals, remove barriers, support international trials and promote patient involvement.
- COVID-19 vaccine developed by Novavax using protein-based technology now approved for GB use and will be subject to the same high standards of vigilance.
- Quality testing of COVID-19 vaccine batches continues in our laboratories with over 210 million doses now being NIBSC certificated for UK and worldwide use.
- Following launch of MHRA Patient Involvement Strategy, Executive Team has activated work on priorities including diversity of Patient Group Consultative Forum.
- Public consultation on reclassifying a locally acting Hormone Replacement Therapy from prescription only to pharmacy availability – potentially a first OTC.
- New guidelines on e-cigarettes as licensed products for smoking cessation have stimulated manufacturers' interest in applying - we are advising on requirements.

1. HEALTHCARE ACCESS

COVID-19 vaccines and therapeutics

1.1 We have now approved the Nuvaxovid vaccine developed by Novavax for GB use, providing access to a fifth COVID-19 vaccine. Nuvaxovid is a protein-based vaccine more akin to traditional vaccine formats. Our approval followed a rigorous rolling review of the safety, quality and effectiveness of this vaccine, and expert advice from the Commission on Human Medicines. Work is ongoing on the evidence of effectiveness, quality and safety of the Valneva vaccine including use of immuno-bridging studies.

1.2 The MHRA continues to engage with companies developing therapeutic products for the treatment of COVID-19. Following the recent approvals of molnupiravir and Paxlovid, we have updated the approval of remdesivir (Veklury) to extend its used to adults with pneumonia not requiring supplemental oxygen. We also approved the use of tocilizumab (RoActemra) for the treatment for COVID-19. Tocilizumab is a medicine already approved for the treatment of certain inflammatory conditions. Use of molnupiravir within 5 days of COVID-19 symptoms is being further evaluated in the PANORAMIC trial.

Innovative Licensing and Access Pathway

1.3 The Innovative Licensing and Access Pathway (ILAP) received 5 Innovation Passport applications during January. The new ILAP digital portal for Innovation Passport and Target Development Profile applications was launched on the 24 January. Additional information on genomic medicines has been included on the ILAP webpage. A Summit meeting on 19 January brought together stakeholders from UK Health Technology Assessment bodies, the National Institute of Health Research, the NHS, industry and patient groups. The agenda covered key learnings during the first year of operation, how the current procedures can be strengthened and development of an expedited medical devices pathway. The ILAP partners are now updating guidance for applicants, developing case studies, considering resource strategies and supporting the work on the medical devices expedited pathway.

Clinical Trials

1.4 On 17 January 2022 the MHRA launched an eight-week public consultation on legislative proposals to streamline clinical trials approvals, enable innovation, enhance clinical trials transparency, enable greater risk proportionality, and promote patient and public involvement. The proposals aim to improve and strengthen the UK clinical trials legislation (the Medicines for Human Use (Clinical Trials) Regulations 2004 as amended), to help us make the UK the best place to research and develop safe and innovative medicines. From 1 January 2022, the MHRA and research ethics committee 'combined review' became the way all new applications for medicine clinical trials will be handled in the UK. Combined review offers applicants and trial sponsors a single application route and a coordinated review, leading to a single UK decision in a faster overall timeline than the previous separate processes.

Influenza vaccine

1.5 The 33rd Meeting between WHO Essential Research Laboratories, Collaborating Centres and influenza vaccine manufacturers was hosted from 11-14 January, with more than 100 participants from across many time zones attending virtually. The agenda included a review of the ongoing influenza vaccine production campaign, updates on the global influenza epidemiology, and provision of candidate vaccine viruses and reference reagents by laboratories such as NIBSC. In addition, sessions were dedicated to WHO's Pandemic Influenza Vaccine Response Operational Plan and the impact of the Nagoya Protocol on Access and Benefit-sharing on influenza vaccine production.

Vaccines against plague

1.6 Innovate UK has awarded a grant to the MHRA's vaccine group. Starting in April the funding will enable the team to collaborate with scientists at Porton Down and Institut Pasteur de Madagascar to develop an International Standard for anti-Plague Immunoglobulin. Institut Pasteur de Madagascar is a WHO Collaborating Centre on Plague and is located in a country that has experienced seasonal outbreaks of this disease. The development of an International Standard for anti-Plague Immunoglobulin will be a timely development for such a reference material to support measuring plague vaccine efficacy, as a novel experimental vaccine developed by the Oxford Vaccine Group (Plavac) is entering Phase 1 clinical trials.

Women's health

1.7 We launched a public consultation to seek the views on the proposal to reclassify a locally acting hormone replacement therapy product, estradiol, from prescription only supply to pharmacy availability. The Commission on Human Medicines has advised that the product can be safely supplied under the supervision of a pharmacist. The consultation runs until 23 February 2022 and we are encouraging responses from a wide range of stakeholders. Vaginal tablets containing oestradiol will continue to be available on prescription. If this reclassification proceeds it would be the first locally acting HRT product to be reclassified and will support the wider government agenda on women's health.

Smoking cessation

1.8 Following our recent announcement that we seek to encourage authorisation of e-cigarettes and other inhaled nicotine products as medicines for smoking cessation, we have been advising a number of companies who wish to submit marketing authorisation applications for these products. One aspect of the advice is that these products are a combination of a drug (nicotine) and a medical device. Two products have been authorised to date but are not currently marketed in UK. This priority work is in line with the government's ambition to be smoke-free by 2030. As stated in the DHSC 2017 Tobacco Control Plan, the evidence is clear that e-cigarettes are significantly less harmful to health than smoking tobacco.

2. PARTNERSHIPS NATIONAL AND INTERNATIONAL

Project Orbis

2.1 The MHRA is now a full participant in Project Orbis, alongside the regulatory authorities of Australia, Canada, Singapore, Switzerland and Brazil. Project Orbis is a programme coordinated by the US Food and Drug Administration (FDA) to review and approve promising cancer treatments. We have completed assessment of several novel products and new indications, and sought advice from the CHM. In January, a variation for Tecentriq (Atezolizumab) to include the new indication for early stage non-small cell lung cancer (NSCLC) was granted. This work featured in several media articles on 4 February, World Cancer Day.

Access Consortium

2.2 Our work in the Access Consortium (comprising Australia, Canada, Switzerland and Singapore) is expanding, and we are currently participating in two procedures as part of the New Active Substance Work Sharing Initiative (with numerous other submissions planned). We are working closely with other agencies as part of the COVID-19 Vaccines and Therapeutics Working Group, and also collaborating with other agencies via the Generic Medicines Working Group, the Biosimilars Working group and the Information Technology Working Group. Progress is being made on introducing a Clinical Trials Working Group and a Joint Scientific Advice Working Group with MHRA currently chairing both groups.

Strategic Data Partnerships

2.3 Over the past year, CPRD has been working with one of the GP software suppliers, EMIS, to migrate from our existing EMIS data flows to their new cloud-based EMIS-X Analytics platform. We have also been working in collaboration with Brunel University on extending previously developed synthetic data generation methods to detect and correct biases in healthcare data that may affect algorithm performance. The novel 'BayesBoost' approach identifies under-represented subgroups in the data and then 'boosts' these subgroups using synthetic data generation methods. This method helps algorithm developers to understand their data and correct for any biases identified. We will continue to monitor the progress of these experiments to mitigate biases in data and understand how this impacts product performance.

3. PATIENT SAFETY

Safety of COVID-19 vaccines

3.1 The overwhelming majority of reports of suspected adverse reactions associated with COVID-19 vaccines in use in UK continue to relate to injection-site reactions (sore arm) and generalised symptoms such as 'flu-like' illness, headache, chills, fatigue (tiredness), nausea (feeling sick), fever, dizziness, weakness, aching muscles, and rapid heartbeat. Generally, these happen shortly after the vaccination and are not associated with more serious or lasting illness. The reporting rates for third or booster doses of COVID-19 Pfizer/BioNTech Vaccine and COVID-19 Vaccine Moderna are lower than those observed for first and second doses of these vaccines.

3.2 Whilst reports of Bell's Palsy following COVID-19 vaccination are rare, the latest available data shows that there may be a very small increase in risk following COVID-19 vaccination. To raise awareness of this potential adverse event, information has been included in the product information for COVID-19 Vaccine AstraZeneca, COVID-19 Vaccine Pfizer/BioNTech and COVID-19 Vaccine Moderna. We have also reviewed reports of suspected transverse myelitis (TM), a rare disorder of spinal cord inflammation. Whilst the incidence rate of this adverse event with any of the COVID-19 vaccines used in the UK remains extremely rare, due to the serious nature of this adverse event and as a precaution, the product information has been updated to raise awareness of the signs and symptoms associated with TM.

SafetyConnect vigilance database

3.3 Development of the new SafetyConnect vigilance database, which will support safety monitoring of medicines, medical devices, blood products and also product quality defects, is at an advanced stage. The complexity of the programme's requirements, and the volume of safety data being migrated to the new systems, together with the necessary prioritisation of COVID-19 related work, has meant that a go-live date of 27 June 2022 is now envisaged. This plan ensures completion of the in-scope development of the current system and accommodates the necessary time to provide assurance of this critical safety system, whilst staying within the programme's approved budget. SafetyConnect will represent a major step forward in use of available technology to deliver a responsive reporting system which meets user needs.

Criminal Enforcement Unit

3.4 The MHRA's new Criminal Enforcement Unit (CEU), a key deliverable of organisational transformation, incorporates enhanced cybercrime and preventative capabilities which will be 'switched-on' in coming months as recruitment is completed. The CEU's financial investigators obtained a series of Account Freezing Orders which will remove the proceeds of crime from subjects implicated in the illegal sale and supply of medicinal products. Ongoing investigative work resulted in the Crown Prosecution Service authorising charges relating to unlawful supply of controlled drugs and prescription-only medicines. A long running joint investigation with the Metropolitan Police Service culminated in defendants pleading guilty to regulatory offences. The outcome of this case is likely to act as a significant deterrent against non-compliance for companies involved in the manufacturing of medicines.

Compliance

3.5 In January, the Inspection Action Group (IAG) considered regulatory action against three licence holders where critical non-compliances in Good Manufacturing Practice or Good Distribution Practice were identified during inspections. Recommendations were made which resulted in two suspensions being issued in this period, both for licensed wholesalers. Information regarding the suspensions can be found on our website. The IAG and Inspectorate continue to work with companies seeking to address deficiencies, liaising with DHSC in respect of critical supply concerns.

Orphaned Device Manufactures

3.6 At the end of December 2021, the Approved Bodies team completed its work supporting Orphaned manufacturers (approximately 150 manufacturers who lost their Notified Body, when they ceased to operate and required our support for an interim period to continue placing their devices on the market whilst obtaining a new Notified or Approved Body). This has represented a significant piece of work for the team over the past three years. By 31 December 2021, all but 3 manufacturers have obtained CE or UKCA marking. Those who have not brought themselves back into compliance have been notified that our support has been withdrawn and they will no longer be able to place their medical devices on the GB market.

4. PATIENT INVOLVEMENT

Safety review of Isotretinoin

4.1 The Isotretinoin Expert Working Group's review of psychiatric and sexual side effects was considered by the CHM in December. Patients, their families and other stakeholders have been an integral part of the review of the safety of isotretinoin. The perspectives provided by patients and families, and the views and experiences shared with the Isotretinoin Expert Working Group through the call for information and series of meetings, has provided valuable information to the Review. The process is currently ongoing, and the report of the review will be published once completed. Patients and stakeholders will be kept up-to-date and involved in the process.

Patient Involvement Strategy

4.2 Following publication of our Patient Involvement Strategy at the end of September 2021, we now have over twenty individual workstreams. These have been prioritised by the Executive Committee, and a top five identified each with a Chief Officer responsible for overseeing delivery. These include:

i. Improving our understanding of patient perception of risk/benefit of medicines and devices
ii. Embed Patient Reported Outcome Measures in evaluation procedures
iii. Transform patient communications to be more accessible and understandable
iv. Improve the diversity and representativeness of our patient pool
v. Improve patient representation on committees and groups.

Every workstream in the strategy is being fully scoped with clear outcomes and key milestones agreed for each, and cross-agency delivery teams have been established.

5. DYNAMIC ORGANISATION

Transformation Programme

5.1 Following implementation of the new One Agency organisational structure on 10 January, we are now focussing on progressing recruitment activity and completing internal selection processes, with the aim to fully populate the new structure by the end of this financial year. Operationalisation of the One Agency organisation is dependent on the successful completion of this activity. To address this, we have developed a recruitment plan which includes sourcing additional support to ensure priority vacancies are filled. We are also monitoring progress closely and senior leaders are undertaking mitigation actions which are kept under constant review.

Optimising Agency services

5.2 Our work on transforming Agency services has been ramped up with identification of the priority services for re-engineering, with engagement with service users under way to establish what is most valued. A subsequent discovery workshop has been held to focus on measures to speed up patient access to established products. The ideas that emerged are expected to yield measurable impacts in both the short and medium term. We will further develop these over the coming weeks, including sharing emerging proposals and undertaking co-design with industry service users through February and March.

Health and Safety

5.3 Staff changes arising from the Transformation programme mean that there are changes to the roles of the staff who support the Agency's vitally important Health and Safety system, in particular on the South Mimms site. A gap analysis is under way to ensure that no new Health and Safety risks arise or known risks worsen during the transformation. An updated Health and Safety staff network is being developed and supported through additional training of staff in new roles at all levels of the organisation.

New applications outsourcing contract

5.4 After several months of procurement process, the Agency has awarded the supplier for the Agency's new applications outsourcing contract. The contract covers both the continued running and maintenance of our regulatory applications, as well as additional optional services to help us deliver new services and technology to support a new regulatory management system. The successful supplier, Accenture, has worked with the Agency for a number of years, but demonstrated a fresh commitment to our mission and has stepped forward, in recognition of the importance of our work, offering significant cost savings to help the Agency deliver critical technology solutions in challenging times. Our goal is to work together to deliver the next generation of systems that will do much more than simply replicate the 'digitised paper' processes that exist in some areas today. This is an exciting step forward in realising some of the ambitions of our Agency's transformation as set out in the Digital Data and Technology strategy.

6. FINANCIAL SUSTAINABILITY

Fees Strategy

6.1 We have commissioned market and pricing sensitivity research to help us to understand – in key product and service areas – the external factors that we should consider in reviewing and setting prices or fees for our services. In addition, the research will also review internal limitations and parameters (such as the Managing Public Money policy) which in turn will inform the development of a principle-led pricing model for the Agency to use when considering statutory and non-statutory fees setting. Following project initiation, we have reviewed possible product and service areas and considered methodologies with fieldwork starting shortly. The project is on target to complete before the end of March 2022.

Trading fund transition

6.2 On 1 February, the Statutory Instrument which terminates the MHRA Trading Fund status was laid in Parliament and will come in to force on 1 April 2022. A project plan has been prepared and is under review by the Executive Committee. Following a helpful review of our progress by the Audit and Risk Assurance Committee last month, we have strengthened the work on the cultural and financial management capability aspects of the plan.

Spending Review

6.3 We have had some positive news from DHSC on our bids for COVID-19 funding, primarily in relation to safety and surveillance and vaccines. We have been asked to further refine some of our other bids for funding in this area. We still await the outcome of our overall Spending Review bid which is critical for our funding in 2022/23.

7. AGENCY PRIORITIES

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

i. Recruiting appropriately skilled staff to the vacant roles in the Transformed Agency, and supporting the new One Agency Leadership Group to provide dynamic leadership in order to realise the current opportunities, including a major review of Agency's services.

ii. Progressing the Patient Involvement Strategy priority objectives with the aim of achieving measurable and meaningful outcomes.

iii. A clear plan for financial sustainability as the Agency transitions from Trading Fund status to operating within the accounting boundary of the DHSC, with a focus on the Fees Review.

iv. Building on the wealth of input and direction from the recent stakeholder Summit meeting, in order to develop the Innovative Licensing & Access Pathway and accelerate establishing a similar pathway for innovative medical devices.

v. Continue to strengthen our national and international partnerships, aiming to achieve meaningful outcomes in terms of UK patient access to innovative healthcare products.

Dame June Raine
CEO
February 2022

Medicines & Healthcare products Regulatory Agency

BOARD MEETING HELD IN PUBLIC

15 February 2022

Title	How much of the Delivery Plan have we achieved from April to December 2021?
Board Sponsor	Jon Fundrey
Purpose of Paper	Assurance

How much of the Delivery Plan have we achieved from April to December 2021?

1. Executive Summary

1.1 This report provides an update on Delivery Plan implementation during the third quarter (Q3) of the reporting year, which was scheduled as one of the busiest of the year. We successfully delivered seven items, two of which were before they were due. These reflect deliverables on innovation, access, safety and partnerships and reflect the move to the establishment of the 'One Agency' future operating model.

1.2 We have brought three items back on track (from amber to green) and improved the delivery confidence of a further two from red to amber. However, a combination of transformation staffing impacts and dependencies have reduced progress and six items, due in Q3, are now expected to be achieved in the final quarter of the year. The number of items that are off-track has risen from 16 to 25; 15 of these are new and 10 have rolled over from Q2 and have mitigations in hand.

2. Introduction

2.1 The Executive Committee (ExCo) and its Delivery and Performance Committee (DPC) run the Agency's performance reporting process, which tracks and manages the implementation of the Delivery Plan. Each item in the plan has a lead who provides a quarterly update including a Red, Amber, Green (RAG) rating based on confidence in successful delivery and an action plan to correct anything that is going off track. This is in addition to any pre-existing governance arrangements for each deliverable. Red and Amber items are also cross-checked against the Corporate Risk Register. This information is collated quarterly, peer-reviewed by the DPC and then the ExCo, actions are agreed to help keep work on track and an overview is submitted to the Board for assurance.

3. Discussion

Performance in Q3

3.1 There were 11 items due to be delivered in Q3 and the status of each is summarised in table 2. We successfully delivered seven items, two earlier than planned. In relation to innovation, a new service was launched to expedite recruitment into clinical trials via data from the Clinical Practice Research Datalink. Regulatory guidance was also published for the first time on clinical trials with a real-world data element. The Innovative Licensing and Access Pathway incorporated a number of new 'tools'. In relation to safety, a new model was delivered for the Devices Expert Advisory Group, including greater lay involvement, and an options appraisal was completed to establish a Yellow Card Biobank to investigate the genomic basis of adverse drug reactions. On partnerships, the Agency's role in the Access Consortium (Australia, Canada, Singapore and Switzerland) was extended in a number of working groups.

3.2 A combination of transformation staffing impacts and dependencies have reduced our progress with the remaining six items due in Q3 slipping into the next quarter but with minor impact, so they have been rated Amber / Green.

3.3 We have also brought three items back on track; **Resolution of any live regulatory issues following EU transition; Agree policy for significantly enhanced transparency regime** and **Publish key guidance documents [for new medical device framework].** These will now be delivered as originally planned. (see Annex A).

3.4 We have also brought two items where delivery was not considered possible (Red) at the end of Q2 back to a position where we consider they will be delivered but later than planned (Amber) This includes our objective to **Finalise our plan to overhaul costly legacy systems by Q1 2022/23 and start to deliver improved service and savings from Q4 2021/22** and **New regulatory management core system** in place by Q1 (see annex A).

3.5 We are largely up-to-date in terms of items running late from last quarter. The work to assess linkages with the WHO slipped and is still due (as noted in table 1) but it has been impacted by the pause on international strategy development. The team have instead focused on having the Agency become a WHO National Regulatory Authority of record for COVID-19 vaccines, which is complete subject to the final WHO signature of the agreement.

3.6 As agreed during Q2, for some priority items we have revised the description of completed deliverables to allow continued reporting on the next steps (hence some items being complete (blue) in Q2 and reverting to having a RAG status in Q3.

Deliverables where there is a new or outstanding high risk of not delivering (Red RAG status) (see table 1)

3.7 **Use of our Cash Reserves** by the end of the financial year is red given the challenge of delivery by the end of Q4. Agreed actions are in hand with senior oversight, but it is unlikely that we will be able to use all our reserves in time.

3.8 The upgrade to our **observational research infrastructure** is dependent on funding being available in 2022/23. Progress has been made on identifying how the CPRD ring-fenced NIHR funds can be retained. Proposals are currently with the Department of Health and Social Care on waiting final confirmation.

3.9 Proposed new medical devices market access framework - **lay relevant SI by end Q1, 2022/23.** Achieving this is now at risk due to the high volume of consultation responses (c900) and the impact of resource being drawn to deal with COVID-19 and transformation. We are working through the consultation responses to understand how they will impact on our original plans.

3.10 **Embed file-sharing** platforms for remote inspections and **visual technology** capabilities as standard part of inspections by Q3, 2022/23. The former is complete. The latter has been removed from the technology roadmap to prioritise more critical systems. This is an internal facing project to support remote inspections and the need for it, as well as other approaches, will now be considered so that a decision can be taken to delay or remove this item from the delivery plan.

Deliverables that are slipping (Amber RAG status) (see table 1)

3.11 **Roll-out automated inspection reports by Q4, 2021/22.** This has been flagged as an issue since Q1 given the need to focus on higher priority work and insufficient inspector resource. Progress has been made in Q3: GMDP roll-out is completed and GLP roll-out is in progress; but GCP and GPvP roll-out remains Amber as there is insufficient staff resource at present. The loss of application support within the Healthcare Quality & Access Group creates an increased risk.

3.12 Publish **laboratory strategy** and long-term plan, including a standards sub-strategy, by Q4 2021/22; and implemented from Q1 2022/23. There has been a slippage in the development of these strategies although work has continued on both. The Board has agreed a delay with the next milestone being an update to them in March 2022. This will mean the Strategy will be further developed in 2022-2023 although elements of it, and the standards sub-strategy, could still be started from the original Q1 2022/23 implementation deadline.

3.13 **Launch staff leadership action plan** by Q2, 2021/22. A paper and baseline plan for Agency-wide leadership development were signed off by ExCo on the 26th January and several leadership development interventions are planned for the final quarter of the year.

3.14 Publish Public Involvement Strategy by Q1 [completed] and **deliver strategy actions** by agreed deadlines. This has been marked as Amber as, while no deadlines have been missed yet, there have been delays to some elements of work given resourcing issues and the impact of transformation. Plans are in hand to address this and the team should be able to catch-up and bring this back on track and green during Q4.

3.15 Deliverables that were reported as already slipping in Q2 look stable. They are summarised in Annex A. There is still sufficient time to deliver these outstanding items. Most are due in the latter quarters of the Delivery Plan and are Amber given the impact of, or dependency on, live Transformation work (i.e. Transformation work itself, work dependant on Transformation outputs or work dependent on the completion of the staff restructure).

3.16 Three items have gone back to Green after efforts by leads and implementation of agreed mitigation eg in Q3 the UK and EU reached an in-principle agreement on supplying medicine to NI. This moved the work to “resolve regulatory issues following EU transition” (a key risk on the CRR) from Amber to Green; and it was enabled by re-prioritisation and extra staff resource secured following Q1 discussions. The team is now focusing on finalising the deal and the impact of implementation for the Agency.

Plans for Q4

3.17 At the time of writing, the outcome of our Spending Review (SR) bid is still unknown. This is a key dependency for several items and when the outcome of the bid is known, we will assess the impact on the Delivery Plan.

3.18 Further review work is planned for Q4 now Chief Officers are in post and after the delayed outcome of our SR bid is known. This will include a refresh of some deliverables, re-alignment of a small number of items to match the final Chief Officer portfolios and some prioritisation of items to help provide focus and tighter control where it matters. This work will also feed into the planned work to refresh the CRR early in the next reporting year.

3.19 There is likely to be a further “peak” of work as we move to Q4. Despite effort to balance deliverables in the Delivery Plan, Q3 and Q4 2021/22 are busy periods. It is worth noting that 20 items are due in Q4 (currently RAG rated at: two Red, four Amber, one Amber/Green, 13 Green) and it will be important to track the Q3 items that have slipped into Q4.

4. Recommendation

4.1 The Executive Committee thoroughly debated and discussed progress made in Q3 and agreed to support refocussing of the red items; the action plans for new Reds and Ambers are sufficient; the Q2 amber items are stable and, thanks to the existing action plans, improvements are showing on four items. It will be important to maintain vigilance in Q4 given wider pressures on the Agency and staff. Further work is planned for the final quarter to review the Delivery Plan for next year and the impact of the SR outcome once known.

4.2 The Board is asked to note this report and provide any comments they might have on the assurance given.

TABLE 1: ISSUES AND HANDLING PLANS

This table shows the 16 notable issues and their current handling plans. Note that Annex A also contains 9 amber items that are outstanding from Q2 but where mitigations (agreed during the Q2 process) to bring them back to green are still in hand.

Delivery Plan Deliverable	Due	Q1	Q2	Q3
New or outstanding Red items				
1. Use cash reserves to fund necessary systems investments, operational deficits and restructuring costs until the end of our Trading Fund status. (Rose Braithwaite) ExCo has agreed a plan to ensure optimal use of reserves and is closely tracking it. To date £3.3m has been approved, leaving a closing balance of c.£11-13m. Across the agency SMTs are continuing to prepare requests and Resources Committee will continue to meet weekly to expedite approvals. Project activity is being reviewed to bring forward activity where possible, however resource constraints, coupled with impact on BAU workload and Transformation, are a complicating factor.	End 21/22	G	R	R
2. Upgrade our **observational research infrastructure** to enable timely and secure delivery of research data services: map out requirements by Q4, 2021/22 and commence implementation of new systems by Q2, 2022/23. (Tim Williams/Puja Myles and Rose Braithwaite) We have completed the deliverable relating to mapping the OR-TRE requirements, but we cannot progress further unless funding is confirmed. To date there has been no confirmation of the SR Bid. In terms of attempting to retain CPRD ring-fenced NIHR funds at the end of 21/22 we have proposed a solution and are awaiting approval by DHSC colleagues.	Q4 21/22	G	A/ R	R
3. Proposed new medical devices market access framework - **lay relevant SI by end Q1, 2022/23.** (Camilla Fleetcroft) We have ongoing challenges re analyst resource with the loan resource currently in place being insufficient. This has been flagged and will be going to the resource committee for consideration. The DHSC Act implementation team are also looking at what additional support they can provide. Project management resource was flagged during the SR, no resource is available internally and therefore a request is going to the Resource Committee.	Q1 22/23	A	A	R
4. Embed file-sharing platforms for remote inspections and **visual technology** capabilities as standard part of inspections by Q3, 2022/23 (James Pound) [split into] File-sharing platforms embedded into BAU: Blue (complete) Visual technologies: during Q3 TD^3 informed us that, as part of the tech roadmap review, there are resourcing (TD^3) and sustainability (ongoing funding) concerns and this work cannot be supported anymore, so we are unable to deliver it. Several visual technologies have been trialled and we remain committed to working with TD^3 to define a tool for BAU roll-out. We propose the decision to remove this from the TD^3 roadmap is reviewed as part of Transformation implementation, and that consideration is given to inclusion of a request for BAU funding as part of a future SR bid.	Q3 22/23	G	G	
• File-sharing platforms (Blue)				B
• Remote visual technology (Red)				R
New or outstanding Amber or Amber/green items				
5. Roll-out **automated inspection reports** by Q4, 2021/22 (James Pound) [split into] As reported previously, higher priority work and insufficient inspector resource in all GxP areas was making delivery by the deadline difficult. ExCo didn't accept the request to extend the deadline to Q1 22/23. Progress has been made in some areas	Q4 21/22	A	A	

for Q3: GMDP roll-out completed and GLP roll-out in progress. GCP and GPvP roll-out remains Amber as there is insufficient resource at present due to the resourcing challenge. In addition to this, the loss of application support within IES (due to transformation the relevant technology support team will no longer exist) creates an increased risk.				
• GMDP and GLP (Blue)				B
• GCP and GPvP (Amber)				A
6. Publish **laboratory strategy** and long-term plan, including a standards sub-strategy, by Q4 2021/22; and implemented from Q1 2022/23. (Marc Bailey / James Pound) There has been a slippage in the development of these strategies although work has continued on both. The Board has agreed a delay with the next milestone being an update to them in March 2022. This will mean the Strategy will be further developed in 2022-2023 although elements of it, and the standards sub-strategy, could still be started from the original Q1 2022/23 implementation deadline. The update to the Board will include timescales for approval.	Q4 21/22	G	G	A
7. Launch **staff leadership action** plan by Q2, 2021/22. (Vanessa Birchall-Scott) Agreed plan and comms ready but delay to realising Board and ExCo development plans due to other transformation priorities and expanded senior leaders development plans (linked to reserves funding opportunity) at commission stage. Implementation of initial plans for ExCo, Board and expanded plans for senior leaders all now due in Q4.	Q2 21/22	G	B	A
8. Publish Public Involvement Strategy by Q1 [done], and **deliver strategy actions** by agreed deadlines (progress is being reported directly to ExCo and PSEC on specific deliverables and dates; summary progress will be reported here) (Rachel Bosworth) The ExCo has now approved a plan to activate the strategy, which includes a prioritised list of actions with owners and deadlines. Progress has been made on workstreams and no deadlines have been missed yet but there have been delays to some aspects given resourcing issues and the impact of transformation. Plans are in hand to address these and we should be able to catch up lost time and bring this back on track, but it should be Amber in the meantime.	Tbc	G	B	A
9. Pilot voluntary 'pre-inspection' checks to fast track new applications for manufacturing licences and piloting the use of consultants as '**compliance monitors**' in remediation cases by Q3, 2021/22 (James Pound) Progress has been made but delivery has slipped to Q4. We do not expect this will have a significant negative impact as benefits will occur in the medium-long term. Compliance monitors: interim consultation with stakeholders done and outline processes and stakeholder comms developed to implement pilot. First phase of GMP pilot planned for Q4 21/22 to evaluate use of CM and obtain evidence to further improve process and justify any roll-out to BAU. Pre-inspection checks: pilot for GMP planned for Q4 21/22, subject to sufficient resource availability from Process Licensing team during transition to new FOM.	Q3 21/22	G	G	A/ G
10. Reduce regulatory burden by identifying which **flexibilities introduced for COVID-19** are safe to embed by Q3, 2021/22. (Rachel Arrundale) Work nearly done using short-term appointment but they have left and relevant lead is temporarily reprioritised to COVID-19 authorisation, hence this slipped. Stakeholders consulted initially but given passage of time we'll need to go back to them to check their views haven't changed. Aiming to complete in Q4.	Q3 21/22	G	G	A/ G
11. Put in place new legislation to ensure safe access to innovative products and to protect public health: timings agreed and public consultations begin from Q1, 2021/22;	Q3 21/22	A	G	

launch all consultations by end Q3, 2021/22; publish all responses by end Q4, 2021/22; and lay all SIs by end Q1, 2022/23. (Rachel Arrundale) [split into] Good progress on new SIs. EAMS and PoCM consultations have concluded and we anticipate the new EAMS SI to be laid in early Feb, ahead of time. Clinical trial consultation is however due for launch in Jan, a month after Q3 deadline – hence Amber/green. This was due to the need for additional consultation, via an Expert Task and Finish group, to address Ministerial interests. Both the PoCM and Clinical Trials regulations will now be affected by a gap in the ability to lay SIs, during the NI election period. This means that these SIs are now likely to be laid in Q3, 2022/2023. The NI election period has had a similar impact on plans for all the MMD Act SIs, and Ministers have been advised. In addition, there has been good progress on the clause in the Health and Care Bill to enable medicine information systems to be set up; this commenced in the Lords in Jan.				
• Clinical Trials (Amber/green)				A/G
• EAMS, Valproate and PoCM (Green)				G
12. Review teratogen use during pregnancy, review other regulators strategies by Q3; independent patient and stakeholder input and expert advice by Q4; c. and, if needed, updated action / guidance by Q2, 2022/23. (Angeliki Siapkara) On track but current milestone slipped due to competing priorities from COVID vaccine safety monitoring. Current phase should be completed by early Q4 so should only have minor impact on next milestones or overall deadline for finishing the work.	Q3 21/22	G	G	A/G
13. Deliver our data sharing strategy across the health sector, underpinned with robust security standards and privacy by design by Q3, 2021/22. (Diana McAuley) We have been working with NIHR and HRA on the strategy but delays in onboarding a data architect to support the work has resulted in slippage. They have since joined, we have caught up a little and will be able to publish in March, slipping into Q4.	Q3 21/22	G	G	A/G
14. Deliver **2 NIHR funded, real world pragmatic clinical trials** with the first patients randomised in both trials by Q3, 2021/22. (Tim Williams/Puja Myles) ASYMPTOMATIC Trial: approved and expecting patients imminently, progress delayed by 3 months mainly due to client issues – hence Amber/green not Blue. DaRe2THINK Trial: open and recruiting (over 110 patients enrolled at time of writing) and we now aim to increase recruitment rates and numbers of involved practices.	Q3 21/22	G	G	A/G
15. / **16**. Development of an **international strategy** by Q1, 2021/22. [and] Full assessment of **linkages needed with the WHO**, including in the context of our biological and control standards work by Q2, 2021/22. (Glenn Wells/Jack Turner) ExCo agreed to pause the strategy to allow further development. Obviously wider work on international continues and the team has succeeded in the Agency becoming a WHO National Regulatory Authority of record for COVID-19 vaccines, subject to the final WHO signature of the agreement. Amber / Green as the impact is low. Next steps are strategy development and to review bilat and multilateral (including WHO) relationships. This work will need to be assessed against other work priorities, but is likely to be able to move forward as staff are recruited into vacant positions.	Q1 21/22 & Q2 21/22	G	A/G	A/G

TABLE 2: STATUS OF ITEMS DUE FOR DELIVERY IN Q3

This table summarises the status of the 11 items due in Q3 and 2 items delivered early. Of the 11, 5 were delivered on time and 6 are experiencing minor slippage and in a way that has low impact on the outcome of the work. All late items are on track for delivery in Q4 and the impact of the delays has been assessed as minor.

Deliverable	Status and any next steps
Blue - Completed	
Scale up 2 ***pilot primary care common data models*** *to facilitate PV across different data sources: Observational Medical Outcomes Partnership model by Q1, 2022/23; 'Sentinel' model by Q2, 2022/23.* (Tim Williams/Puja Myles)	Completed early. Scaled up Pilot Observational Medical Outcomes Partnership Common Data Model & Sentinel Common Data Model databases complete, validation underway to inform future direction for next refresh in 2022/23.
Publish ***guidance on points to consider when using trial designs*** *with a real-world data element to support a licence application by Q4, 2021/22.* (David Brown)	Completed early. Ad hoc CHM RWD met in Oct, draft guidelines agreed and published on 16 Dec. Cross-Agency RWD group is now beginning work on a new guideline on external control groups.
Launch new service that assists in the ***rapid recruitment of patients into commercial clinical trials,*** *with first contract in place by Q3, 2021/22 and offer this service to companies as standard by Q2, 2022/23.* (Tim Williams/Puja Myles)	Service launched; 3 commercial trials have been supported as part of the post launch pilot service. Experience of delivering this service as well as metrics are being collated. There is a current focus on lessons learned with a view to enhancing the service moving forwards.
Further develop the ***ILAP concepts and tools****, in collaboration with the NICE and the SMC to create a world-class first port of call for medicines development and access by Q3, 2021/22.* (Dan O'Connor)	ILAP has been operational for a year and a summit will be held in Jan to consider progress and future direction. A new digital offer for applications providing enhanced operability for industry and efficiencies in automation for partners is due to be launched end of Jan 2022.
Improve model of ***DEAC and its EAG*** *by Q3, 2021/22 (plan to be agreed by Q3), to ensure greater involvement of independent, scientific, technical, lay and clinical experts in regulatory decision making.* (Janine Jolly)	The plan for the new model of DEAC has now been approved by DEAC. A update paper is due for the CEO / ExCo. The current DEAC will continue until June 2022. We will recruit to a refreshed DEAC that will serve for a year (from June 2022). Final statutory DEAC should be in place by June 2023.
Deliver an options appraisal for our ***project to investigate the role of genetics in the development of adverse drug and vaccine reactions*** *by Q3, 2021/22.* (Mick Foy)	Options Appraisal for a YC Biobank complete. Scoping activities continuing in Q4 22/23 to secure funding and move forwards with activities for set-up. Update of deliverable to follow.
Greater ***international regulatory collaboration*** *and alignment with Access Consortium so patients benefit from timely access to high quality, safe and effective medicines from Q3 2021/22.* (Jack Turner)	Now active members of the Access Consortium, participating in several working groups. We have made suggestions for expanding the remit and will continue to build on progress.

Amber / Green – minor slippage and / or minor impact	
*Deliver **two NIHR funded, real world pragmatic clinical trials** through our innovative data-enabled clinical trials platform, with the first patients randomised in both trials by Q3, 2021/22.* (Tim Williams/Puja Myles)	See table 1 - DaRe2THINK trial fully open and recruiting and ASYMPTOMATIC trial approved and open but slightly behind in recruitment.
***Review of teratogen use during** pregnancy, and consideration of the strategies of other regulators **by Q3, 2021/22**; b. with independent patient and stakeholder input and expert advice by Q4, 2021/22; c. and, if required, updated action and guidance by Q2, 2022/23.* (Angeliki Siapkara)	See table 1 – minor slippage to early Q4 but unlikely to have downstream impact on next milestones or final delivery date.
*Put in place new legislation to ensure safe access to innovative products and to protect public health: timings agreed and public consultations begin from Q1, 2021/22; **launch all consultations by end Q3, 2021/22**; Publish all responses by end Q4, 2021/22; and lay all SIs by end Q1, 2022/23.* (Rachel Arrundale)	See table 1 – slippage on one aspect of the work ie clinical trials consultation run in January not Q3; other areas on track.
*Deliver our **data sharing strategy** across the health sector, underpinned with robust security standards and privacy by design by Q3, 2021/22*. (Diana McAuley)	See table 1 – progress made but delivery slipped from Q3 to March.
*Reduce regulatory burden by working with stakeholders to identify which **flexibilities introduced in response to COVID-19** are safe to embed by Q3, 2021/22.* (Rachel Arrundale)	See table 1 – progress made but slipped to Q4, impact negligible as regulatory flexibilities are already in place and we're likely to recommend keeping them as they are.
***Pilot voluntary 'pre-inspection'** checks to fast track new applications for manufacturing licences and piloting the use of consultants as '**compliance monitors'** in remediation cases by Q3, 2021/22*. (James Pound)	See table 1 – progress made but slipped to Q4, impact also judged to be low given benefits are expected in the medium- to long-term.

ANNEX A: OUTSTANDING AMBERS AND ITEMS BROUGHT BACK TO GREEN

This table provides an update on the 9 items that are still Amber but have agreed mitigation in hand. Mitigations were discussed and agreed during the Q2 process. Also included are the 3 items that have been brought back to Green.

Delivery Plan Deliverable	Due	Q1	Q2	Q3
Amber – mitigations in hand				
Deliver accompanying **Transformation Programme** and organisational redesign (staffing, governance, structures, processes) by Q4, 2021/22 and post implementation support including benefits realisation from April 2022 onwards. [and] **Implement organisational design**, creating a new, leaner structure for the organisation and balancing our costs by Q3, 2022/23. (Davinder Virdi) Approval given by ExCo / Board to implement new structure on 10 Jan 2022. Team now focused on HR critical path, significant time and capacity being consumed by it and there has been slippage, corrective actions in hand. Critical services and process redesign work has been paused to prioritise HR transformation activities; work due to continue in Jan 2022. Have begun to set up governance for implementation phase and closer links to digital We continue to manage dependencies for balancing costs by Q3, 2022/23. Significant risk that delays to HR critical path will push FTE reduction benefits into new financial year but corrective action in hand. SR remains key dependency. More work to do on fees and to reduce expenditure. 10SC accommodation footprint being reduced. Programme Business Case due for DHSC Investment Committee shortly. Next steps: • The outcomes of the mapping and matching process will give a final view on pay. • Rephasing of current programme of activity being considered by Technology, which may result in changes to project spend across the 3-year period. • Over the next 2 months, the Agency will also receive the outcomes of the SR and the situation on fees will be clearer.	Q4 21/22 Q3, 22/23	A	A	A
Deliver **HR support and guidance to staff** during organisational restructuring throughout Q1-Q4, 2021/22. (Vanessa Birchall-Scott) Note link with above; Amber given peak period but plans in hand. Consultation closure and related comms with staff and representatives, plus individual outcomes decisions and related correspondence underway. Implementation in progress along with support for those at risk of redundancy or going through selection. Opportunities to query outcome decisions and ask questions and ongoing support in place.	Q1-Q4, 21/22	G	A	A
Finalise our plan to **overhaul costly legacy systems** by Q1 2022/23 and start to deliver improved service and savings from Q4 2021/22. (Rob Knowles) Overhaul of legacy systems: finalisation of plan now forecast to complete in Q1 2022/23 so moved from Red to Amber. Engagement with the new supplier to engross and finalise the contract will start in Jan 2022. Savings will be delivered from Q4 2021/22, with additional savings for having been identified through the support contract. Most savings are dependent on replacement of legacy IT estate (expected to take 15 months) and enabling new ways of working being developed by Transformation through Q4 FY22/23. We are waiting confirmation from DHSC on proceeding to the standstill stage and the next steps.	Q1 22/23	G	R	A
New **regulatory management core system** in place by Q1, 2023/24.(Avnesh Pandya) New due date of Q1 FY23/24 agreed with ExCo so move from Red to Amber. Following engagement during supplier outsourcing procurement, a timescale of 15 months from discovery work to completion of the initial release was indicated by suppliers. Six main dependencies exist and are being managed: completion of application support and development contract signature (Q4 FY21/22); approval of the Transformation business case (Mar 2022) and agreement of how sub-cases will progress including the new regulatory management system; confirmation of SR funding	Q1 23/24	G	R	A

(Feb 2022); completion of service and process requirements from Transformation for systems development (Mar 2022); and the start of Discovery activities (Q1 FY22/23) to finalise plans for legacy system replacement and the RMS.				
Deliver a new **digital self-service platform** in beta by Q3, 2022/23 and live in Q4 2022/23 that will improve the service patients and customers receive. (Avnesh Pandya) As previously, delays given scope of platform is dependent on outputs from Transformation and the further development of the branding, marketing and business development strategies and teams being formed through the restructure. ExCo agreed to push back the due date to FY22/23. This is also subject to a successful SR bid.	Q3 22/23	G	A	A
Deliver a set of work packages to ensure that **AI as a medical device** is underpinned by robust evidence to enable safer innovation by Q4, 2022/23. (Johan Ordish) We continue to face a resource challenge from delays in formation of the FOM but recruitment now due in Jan 22. Work packages are defined and we are delivering in the meantime. Developments this quarter include: publication of Good Machine Learning Practice Principles with FDA and Health Canada, full draft of the Change Programme roadmap progressing through clearances, first round of legal instructions for statutory changes in hand. The full roadmap for the programme will follow the government response to the public consultation to avoid pre-empting response.	Q4 22/23	A	A	A
Deliver **world-leading approach to inspections** with assurance that products are developed and manufactured to highest standards throughout 2021/22 & 2022/23. (James Pound / Andy Morling) As per previous updates, the inspectorate is insufficiently resourced. Recruitment for 8 FTE in the FOM has been accelerated to mitigate risk of a further reduction in our ability to sustain the risk-based inspection programme. New inspections strategy will be subject to a Board seminar in Q4 21/22 / Q1 22/23. Earliest we could expect a move to Green would be end of Q1 22/23. ILAP spending review bid included 4 GCP & 4 GMP inspectors to support enabling innovation through regulatory reform, which if successful will also contribute to the transformed inspectorate.	21/22 - 22/23	A	A	A
Map the most **important partnerships for delivery** of our 2021-23 objectives and refresh strategic relationships with detailed work programmes developed to maximise reach and impact across the system in place by Q4, 2021/22. (Rachel Arrundale) Work on hold while resource is shifted to support implementation of new fee structure. We do not have the resource to deliver both simultaneously. This work is however captured in the new partnerships structure so will be prioritised post transition. Still possible to be brought back on track within the 2-year period of the Delivery Plan.	Q4 21/22	G	A	A
Brought back to Green in Q3				
Resolution of any live **regulatory issues following EU transition** by Q1, 2022/23. (Rachel Arrundale/Jack Turner) Work is in train to assess the impact of the EU proposals on our regulatory functions. New resource is in place and we have been able to bring this back to Green now.	Q1 22/23	A	A	G
Agree policy for **significantly enhanced transparency regime** for device regulation by Q4, 2021/22; with key elements being delivered over 2022/23. (Tony Sant) Progress has been made on the policy, a consultation was run and we are reviewing the responses now. Note dependency on TD[3] but otherwise can be Green for now.	Q4 21/22	A	A	G
Publish key guidance documents [for new medical device framework] by end Q3, 2022/23 with ongoing engagement with stakeholders over the course of 22/23 to prepare them for the new framework. (Camila Fleetcroft) On track notwithstanding Red status of the SI deliverable. Following agreement of future policies, we will be able to turn our focus to drafting new guidance.	Q3 22/23	A	A	G

ANNEX B: OVERALL RAG SUMMARY FOR Q3

#	Delivery Plan Deliverable	Due	Q1	Q2	Q3
SCIENTIFIC INNOVATION; 2. Deliver public health impact, world-leading research innovation and a unique proposition					
1	Risk-based approach to batch release: guidelines drafted by Q3, 2021/22 implement independent testing based on risk based strategy by Q4 2022/23	Q4, 2022/23	G	G	G
2	Develop and publish our laboratory strategy and long-term plan, including a standards sub-strategy, by Q4 2021/22; and implemented from Q1 2022/23.	Q4, 2021/22	G	G	A
3	Upgrade our observational research infrastructure to enable timely and secure delivery of research data services: map out requirements by Q4, 2021/22 and commence implementation of new systems by Q2, 2022/23.	Q4, 2021/22	G	A/R	R
4	Scale up two pilot primary care common data models to facilitate pharmacovigilance across different data sources: the Observational Medical Outcomes Partnership model by Q1, 2022/23; the 'Sentinel' model by Q2, 2022/2023.	Q1 / Q2, 2022/23	G	G	B
SCIENTIFIC INNOVATION; 3. Overhaul clinical trials system to support innovation and reduce time to approval					
5	Deliver two NIHR funded, real world pragmatic clinical trials through our innovative data-enabled clinical trials platform, with the first patients randomised in both trials by Q3, 2021/2022.	Q3, 2021/22	G	G	A/G
6	Encourage a more innovative and pragmatic approach to clinical trials via an initiative to facilitate the uptake of novel trial designs and a comms effort to tackle the misperceptions that "traditional" clinical trials are always required for a licence by Q4, 2021/22.	Q4, 2021/22	G	G	G
7	a. Launch a new service that assists in the rapid recruitment of patients into commercial clinical trials, with the first contract in place by Q3, 2021/22 and offer this service to companies as standard by Q2, 2022/23	Q3, 2021/22	G	G	B
7	b. and by Q4, 2021/22 achieve 1 in every 4 UK GP practices signed-up to our clinical practice research data service.	Q4, 2021/22	G	B	B
8	Consult on options for changing UK legislation to make conduct of trials generating real-world data easier by Q4, 2021/22.	Q4, 2021/22	G	G	G
9	Publish guidance on points to consider when using trial designs with a real-world data element to support a licence application by Q4, 2021/22.	Q4, 2021/22	G	G	B
10*	Develop use of PROM via involvement in the "Setting International Standards in Analysing Patient-Reported Outcomes and Quality of Life Endpoints Data" international initiative from Q1 to Q4, 2021/22; and work up deliverables in 2022/23.	Q4, 2021/22	G	G	G
11	Deliver NHSX funded synthetic data research project by Q4, 2021/22 and launch prototype synthetic data generation service by Q2, 2022/23	Q4, 2021/22	G	G	G
12	Finalise and promote the ILAP Novel Trial Design Tool in partnership with the wider health ecosystem by Q2, 2022/23.	Q2, 2022/23	G	G	G
13	Deliver a set of work packages to ensure that AI as a medical device is underpinned by robust evidence to enable safer innovation by Q4, 2022/23.	Q4, 2022/23	A	A	A

HEALTHCARE ACCESS; 4. Develop and deliver future strategy and approach for access to medicines and devices					
14*	Put in place new legislation to ensure safe access to innovative products and to protect public health: timings agreed and public consultations begin from Q1, 2021/22; launch all consultations by end Q3, 2021/22; Publish all responses by end Q4, 2021/22; and lay all SIs by end Q1, 2022/23. [split into]	Q3, 2021/22	A	G	
	• Clinical Trails (delayed, consultation expected in Jan)				A/G
	• EAMS, Valproate and PoCM (all on track)				G
14	Consult on a national scheme to replace the FMD's safety features regulation by Q4, 2021/22; [superseded by EU proposal for a 3-year derogation for FMD]	N/A	G	G	N/A
14	Formulation of final post-standstill policy during 2022;	2022	G	G	G
14	Resolution of any live regulatory issues following EU transition by Q1, 2022/23.	Q1, 2022/23	A	A	G
15	Integrate with the HRA and NIHR Clinical Research Network to provide a fast track approval for defined clinical trials - criteria for approval agreed by end Q2, 2021/22; next milestone: deliver pilot to set up phase 1 oncology trials by end Q4 2022/23	New: Q4 2022/23	G	B	G
15	Expand pilot process providing a single decision on research using both a medicine and device to a wider cohort of applicants and develop a process for the combined review of a product by Q1, 2022/23.	Q1, 2022/23	G	G	G
16	Reduce regulatory burden by working with stakeholders to identify which flexibilities introduced in response to COVID-19 are safe to embed by Q3, 2021/22.	Q3, 2021/22	G	G	A/G
17	a. Support access to generics and biosimilars via more global harmonisation in approval standards; seek membership of IPRP from Q3, 2021/22;	Q3, 2021/22	G	B	B
17	b. and take forward discussion of UK Biosimilar guidance in the Access Consortium from Q3, 2021/22.	Q3, 2021/22	G	B	B
18	Develop a mechanism to pilot joint clinical trial approval and clinical trial and licensing scientific and compliance advice via Access Consortium by Q4, 2021/22.	Q4, 2021/22	G	G	G
19*	Further develop the ILAP concepts and tools, in collaboration with the NICE and the SMC to create a world-class first port of call for medicines development and access by Q3, 2021/22.	Q3, 2021/22	G	G	B
20	Ensure integrated UK regulatory pathways for products that combine medicinal products and medical devices; consultation by Q3, 2022/23.	Q3, 2022/23	G	G	G
21	Continued regulation of NI, under the EU regulatory system, working closely with NIE to ensure continued access to life sciences products.	Ongoing	G	G	G
HEALTHCARE ACCESS; 5. Establish a new devices legislative framework to support safe innovation and ongoing access to products					
22*	Publish public consultation covering all key aspects of proposed new market access framework by end Q2, 2021/22 and Publish a consultation response with finalised policy positions by end Q4, 2021/22.	Q4, 2021/22	A	B	A

23*	Lay relevant SI by end Q1, 2022/23.	Q1, 2022/23	A	A	R
24*	Publish key guidance documents by end Q3, 2022/23 with ongoing engagement with stakeholders over the course of 22/23 to prepare them for the new framework.	Q3, 2022/23	A	A	G
PATIENT SAFETY; 6. Deliver a more responsive safety surveillance and risk management system, for all medical products, to keep patients safe					
25*	Complete review on new medical devices signals and risk management process, embed risk assessment template and identify opportunities for patient involvement by end Q1, 2021/22.	Q1, 2021/22	B	B	B
26*	a. Further action on valproate to drive compliance with the PPP. Enhance the valproate registry by extending the established England registry to include all antiepileptics by end of Q2, 2021/22;	Q2, 2021/22	G	B	B
26*	b. and make available a UK-wide digital annual risk acknowledgment form alongside defining the extension of the registry to the whole of the UK by end of Q4, 2021/22.	Q4, 2021/22	G	G	G
26*	Improve model of DEAC and its EAG by Q3, 2021/22, to ensure greater involvement of independent, scientific, technical, lay and clinical experts in regulatory decision making.	Q3, 2021/22	A	G	B
27	Deliver an options appraisal for our project to investigate the role of genetics in the development of adverse drug and vaccine reactions by Q3, 2021/22	Q3, 2021/22	G	G	B
28*	Review of teratogen use during pregnancy, and consideration of the strategies of other regulators by Q3, 2021/22; b. with independent patient and stakeholder input and expert advice by Q4, 2021/22; c. and, if required, updated action and guidance by Q2, 2022/23.	Q3, 2021/22	G	G	A/G
29*	Deliver enhanced signal detection process by Q4, 2021/22; and b. service enhancement and international opportunities to defined in Q4, 2021/22; c. and delivered in 2022/23.	Q4, 2021/22	G	G	G
30*	Agreed policy for a significantly enhanced transparency regime for medical device regulation by Q4, 2021/22; with key elements being delivered over 2022/23.	Q4, 2021/22	A	A	G
PATIENT SAFETY; 7. Deliver innovative interventions to ensure the UK has a secure supply chain providing high quality products					
31	Pilot voluntary 'pre-inspection' checks to fast track new applications for manufacturing licences and piloting the use of consultants as 'compliance monitors' in remediation cases by Q3, 2021/22;	Q3, 2021/22	G	G	A
31	Roll out of automated inspection reports by Q4, 2021/22 [split into]	Q4, 2021/22	A	A	
	• GMDP and GLP				B
	• GCP and GPvP				A
31	Identify new risk-proportionate approaches with our international partners by Q4, 2021/22;	Q4, 2021/22	G	G	G
31	Embed file-sharing platforms for remote inspections and visual technology capabilities as a standard part of inspections by Q3, 2022/23 [split into]	Q3, 2022/23	G	G	
	• File sharing platforms				B

	• Remote visual tech				R
32	Deliver the GB Medicines Verification System, to replace the EU system and enable medicines to be tracked through the supply chain – delivery in partnership with the DHSC and to their timescales when finalised.	Tbc – awaiting DHSC	G	G	G
33*	Deliver a world-leading approach to inspections with assurance that products are developed and manufactured to the highest standards throughout 2021/22 and 2022/23.	Ongoing	A	A	A
34*	Deliver a world-leading approach to enforcement with assurance that prompt action is taken to reduce criminal threats throughout 2021/22 and 2022/23.	Ongoing	G	G	G
DYNAMIC ORGANISATION; 8. Deliver our Transformation Programme to make us a truly world-leading, innovative regulator					
35	Embed Delivery Plan in staff objectives by Q1, 2021/22;	Q1, 2021/22	B	B	B
35	Monitor performance from Q2, 2021/22 with an updated reporting approach;	Q2, 2021/22	G	B	B
35	Review and revise plan with the Department of Health and Social Care by Q1, 2022/23 as part of annual business planning.	Q1, 2022/23	G	G	G
36	Deliver accompanying Transformation Programme and organisational redesign (staffing, governance, structures, processes) by Q4, 2021/22 and post implementation support including benefits realisation from April 2022 onwards.	Q4, 2021/22	A	A	A
DYNAMIC ORGANISATION; 9. Deliver a programme to enhance our leadership capability to attract, retain and develop talent so that we can fuel innovation and drive change					
37	a. Develop an organisational culture action plan by Q1, 2021/22; [reporting now covered by item below]	Q1, 2021/22	B	B	B
37	b. and deliver associated actions; refresh plan in Q1, 2022/23.	Q1, 2022/23	G	G	G
38	Launch staff leadership action plan by Q2, 2021/22.	Q2, 2021/22	G	B	A
39	Deliver HR support and guidance to staff during organisational restructuring throughout Q1-Q4, 2021/22.	Q1-4, 2021/22	G	A	A
40	a. Identify future workforce and talent needs and deliver action to ensure we embed workforce planning by Q2, 2021/22; [reporting now covered in item below]	Q2, 2021/22	G	B	B
40	b. and review workforce in Q1, 2022/23 to identify follow up actions.	Q1, 2022/23	G	G	G
COLLABORATIVE PARTNERS; 10. Leverage international partnerships to drive better outcomes					
41	Development of an international strategy underpinning and aligned to the wider objectives in the Delivery Plan by Q1, 2021/22. [Paused by ExCo but wider work continues]	Q1, 2021/22	B	B	A/G
42	Continuing our collaboration with the EU, through the establishment of the Medicinal Products Working Group, established under the Trade and Cooperation Agreement as a forum for bilateral cooperation that can be built on in future. Q2, 2021/22.	Q2, 2021/22	G	B	G
43	Full assessment of the linkages needed with the WHO, including in the context of our biological and control standards work by Q2, 2021/22; [Slipped given pause to 41]	Q2, 2021/22	G	A	A/G

43	Improve our ability to capture and exchange data with partners by adopting international standards including “Identification of Medicinal Products” regulations by Q2, 2022/23.	Q2, 2022/23	G	G	G
44	Establish greater international regulatory collaboration and alignment with the Access Consortium so patients benefit from timely access to high quality, safe and effective medicines from Q3 2021/22.	Q3 2021/22	G	G	B
45	Deliver a refreshed inspection network that adds strengths and international standing to the work of our inspectorate by Q4, 2021/22.	Q4, 2021/22	G	G	G
46	Collaborating with other country regulators to provide quicker access to the next generation of cutting-edge treatments, while maintaining the highest safety standards by Q4, 2022/23.	Q4, 2022/23	G	G	G
47	Actively engage in ongoing trade negotiations (with the USA, Australia, New Zealand and others), putting forward a positive regulatory agenda and enhancing areas of regulatory cooperation throughout 2021-23 as per the DIT timescales	Ongoing	G	G	G
COLLABORATIVE PARTNERS; 11. Leverage UK healthcare system partnerships to integrate processes and drive better outcomes					
48	Agree a revised Partnership Agreement and a detailed package of work programmes with the NICE, focused on safety and standards, improving timely access to medicines and healthcare products for patients, and the promotion of innovation and growth by Q1, 2021/22; delivery of work in updated partnership agreement	Q1, 2021/22 Ongoing	B	B	G
49	Deliver our data sharing strategy across the health sector, underpinned with robust security standards and privacy by design by Q3, 2021/22.	Q3, 2021/22 slipped to Mar 2022	G	G	A/G
50	Map and identify the most important partnerships for delivery of our 2021-23 objectives and refresh strategic relationships with detailed work programmes developed to maximise reach and impact across the system from Q2 and in place by Q4, 2021/22.	Q4, 2021/22	G	A	A/G
51	Continue delivery of our commitments to the DHSC and ministers throughout 21-23.	Ongoing	G	G	G
52	Run partnerships meetings with the DAs and wider stakeholder groups to inform and involve them about the delivery of their priorities, quarterly throughout 21-23.	Ongoing	G	G	G
COLLABORATIVE PARTNERS; 12. Build public and stakeholder trust in our organisation through a programme of proactive and innovative communications					
53*	Publish our Public Engagement and Involvement Strategy, which sets out how we can best include patients in our work by Q1, 2021/22; and deliver patient strategy actions by agreed deadlines (progress is being reporting directly to ExCo and PSEC on specific deliverables and dates; summary progress will be reported here)	As per action plan	G	B	A
54	Develop and deliver further communications to support the evolution of our COVID-19 vaccines strategy from Q2, 2021/22.	Ongoing	G	G	G
55*	Enhance Customer Service Centre to support effective engagement with patients and customers, enabling them to access the info they need when they need it from Q4, 2021/22.	Q4, 2021/22	G	G	G
56*	Develop and deliver communications to support the launch of new and ongoing activities (products, services, campaigns and issues)	Ongoing	G	G	G

	throughout 2021/22 and 2022/23 (covers all communication deliverables in the plan).				
57*	Issue ongoing, prompt and responsive safety comms, including COVID-19, falsified medicines and devices, safer medicines and devices for women, drug safety issues, reclassifications, product alerts; deliver comms to improve the understanding of and engagement with current and new safety reporting services among patients and HCP, throughout 2021/22 and 2022/23.	Ongoing	G	G	G
FINANCIAL SUSTAINABILITY; 13. Establish a new business model for the future that increases income, reduces costs and improves productivity					
58	Implement organisational design, creating a new, leaner structure for the organisation and balancing our costs by Q3, 2022/23	Q3, 2022/23	A	A	A
59	Use available cash reserves to fund necessary systems investments, operational deficits and restructuring costs until the end of our Trading Fund status at the end of 2021/22.	End 2021/22	G	R	R
60	Develop, consult on (Q3, 2021/22) and implement a new fee structure by Q2, 2022/23. *Nb. typo spotted. New fees are due in April 2023 so dates should be: "Develop, consult on (Q2,2022/23) and implement a new fee structure from Q1 2023/2024)"*	Q2, 2022/23	A	G	G
61	Reduce corporate costs by 15% by the end of 2022/23.	End 2022/23	G	G	G
62	Reduce non-pay costs of £60m by £6m per year through contract renegotiation and contract management by the end of 2022/23.	End 2022/23	G	G	G
FINANCIAL SUSTAINABILITY; 14. Deliver an optimised IT infrastructure to improve our service and reduce our costs with fewer digital technologies					
63	a. Finalise our plan to overhaul costly legacy systems by Q1 2022/23 and start to deliver improved service and savings from Q4 2021/22.	Q3, 2021/22 Revised Q2: Q1, 2022/23 Q4 2021/22	G	R	A
63	b. and to have a new regulatory management core system in place by Q1, 2023/24.	Q3, 2022/23 Revised Q2: Q4 2022/23 Revised Q3: Q1 FY23/24	G	R	A
64*	Deliver a new digital self-service platform in beta by Q3, 2022/23 and live in Q4 2022/23 that will improve the service patients and customers receive.	Q4, 2021/22 Revised Q2: Q3, 2022/23	G	A	A
65	Support revised medical devices regulations, deliver the digital self-service, automation and data platforms required by Q1, 2023/24.	Q1, 2023/24	G	G	G
66	Work with the HRA to deliver an enhanced clinical trials service by Q4, 2022/23.	Q4, 2022/23	G	G	G

SCIENTIFIC INNOVATION				HEALTHCARE ACCESS				PATIENT SAFETY			
	1	2	3		1	2	3		1	2	3
laboratory strategy and long-term plan: publish, including a standards sub-strategy, by Q4 21/22; implemented from Q1 22/23	G	G	A	**New devices legislative** framework: publish consultation by Q2, 21/22; **lay SI by end Q1, 22/23**; and publish guidance by end Q3, 22/23 with stakeholder engagement over 22/23	A	A	R	Deliver enhanced **signal detection process** by Q4, 21/22; and service enhancement and international opportunities delivered in 22/23	G	G	G
ILAP Novel Trial Design Tool: finalise and promote the in partnership with the wider health ecosystem by Q2, 22/23	G	G	G	**Wider legislative evolution** to ensure safe access to innovative products and to protect public health: launch all consultations by end Q3, 21/22	A	G	A / G	**Improve model of DEAC** by Q3, 21/22, to ensure greater involvement of independent, scientific, technical, lay and clinical experts in decision making	A	G	G
UK clinical trials: encourage a more innovative and pragmatic approach by Q4, 21/22: consultation by Q4, 21/22: publish guidance by Q4, 21/22	G	G	G	**Resolution of live regulatory issues following EU** transition by Q1, 22/23 and formulation of final post-standstill policy during 2022	A	A	G	Drive compliance with **valproate** PPP: extend registry to all antiepileptics by end Q2, 21/22; UK-wide digital annual risk form and define extension of registry UK-wide by end Q4, 21/22	G	G	G
Risk-based approach to batch release: guidelines drafted by Q3, 2021/22 and begin implementation of approaches via pilot studies from Q4, 21/22	G	G	G	**Further develop the ILAP**, in collaboration with NICE and SMC to create a world-class first port of call for medicines development and access by Q3, 21/22. Item to be updated with new date following Jan '22 summit]	G	G	B	Agreed policy for a **significantly enhanced transparency regime** for devices by **Q4, 21/22;** with key elements being delivered over 22/23	A	A	G
Develop use of PROM via involvement in the "Setting International Standards in Analysing Patient-Reported Outcomes and Quality of Life Endpoints Data" initiative from Q1 to Q4, 21/22; and work up deliverables in 22/23	G	G	G	**Fast track approval for defined clinical trials** - working with HRA, support the Experimental Cancer Medicine Centre (ECMC) to deliver a pilot to set up phase 1 oncology trials: co-creation of an accelerated pathway by **end of Q4 22/23**	G	B	G	**Review of teratogen** use during pregnancy, review strategies of other regulators by Q3, 21/22; patient and stakeholder input and expert advice by Q4, 221/22; if required, updated action and guidance by Q2, 22/23	G	G	A / G
DYNAMIC ORGANISATION				**COLLABORATIVE PARTNERS**				**FINANCIAL SUSTAINABILITY**			
	1	2	3		1	2	3		1	2	3
Deliver Transformation Programme and organisational redesign (staffing, governance, structures, processes) by Q4, 21/22 and post implementation support including benefits realisation from April 22	A	A	A	Delivery of **International Strategy** actions, closer ties to Access, WHO, and other country regulators to provide quicker access to the next generation of cutting-edge treatments, while maintaining the highest safety standards	G	G	G	Finalise plan to **overhaul costly legacy systems** by Q1, 22/23; start to deliver improved service and savings from Q4, 21/22; [and] have a **new regulatory management system** in place by Q1, 23/24	G	R	A
Implement organisational design, creating a new, leaner structure for the organisation and balancing costs by Q3, 22/23	A	A	A	**Refresh strategic relationships** with programmes of work by Q4, 21/22; continued closer working with NICE; data sharing strategy by Q3, 21/22	G	A	A	Develop, consult on (Q2, 2022/23) and implement **new fee structure** by Q1, 23/24	A	G	G
Launch staff leadership action plan by Q2, 21/22 (blue but work continues as actions are delivered)	G	B	A	Publish **Public Involvement Strategy** by Q1, 21/22 (Blue) and then deliver actions (Amber – no deadlines missed but some delays given resourcing issues and transformation	G	B	A	**Reduce non-pay costs** of £60m by £6m per year via contract renegotiation and contract management by end of 22/23	G	G	G
Identify **future workforce and talent needs** and deliver action to ensure we embed workforce planning by Q2, 21/22; and review workforce in Q1, 22/23 to identify follow up actions	G	G	G	Greater **international regulatory collaboration** and alignment with Access Consortium so patients benefit from timely access to quality, safe and effective medicines from Q3 2021/22.	G	G	B	**Use cash reserves** to fund necessary systems investments, operational deficits and restructuring costs until end of Trading Fund status at the end of 21/22	G	A / R	R

PATIENT INVOLVEMENT
The Delivery Plan has 23 deliverables flagged as examples of work with particular patient interest. The status of these items since Q2 is broadly stable: in Q2 4 were Blue, 14 Green and 5 Amber and in Q3 4 were Blue, 12 Green, 2 Amber/green, 4 Amber and one Red. The work of this underpinning objective is being taken forward via the Agency response to the Cumberlege Review: benefits mapping is underway to further develop measures to monitor the impact of deliverables and ensure improved governance of these important items.

Medicines & Healthcare products Regulatory Agency

BOARD MEETING HELD IN PUBLIC

15 February 2022

Title	How are we performing on Health and Safety compared to best practice?
Board Sponsor	Dr Marc Bailey
Purpose of Paper	Assurance

How are we performing on Health and Safety compared to best practice?

1. Executive Summary

1.1 The paper provides a response to the question posed by the Agency Board to consider how health and safety is managed in the Agency, and especially in assessing against other organisations and reviewing against best practice. The Board is asked to provide strategic direction, and where applicable, approval on the proposals outlined in this paper.

1.2 The Agency strives to achieve excellence in all aspects of the business/agency activities. We have internal and external assessment of Health & Safety (H&S) performance which demonstrates our commitment to achieve best practice. Positive relationship with the Regulators (Health & Safety Executive (HSE), Environment Agency and Home Office) and feedback from British Standards Institution (BSI) remains positive.

1.3 Key proposals listed in order of priority in Section 3 of the paper offer suggestions for building on existing good practice and committing to the requirement for continual improvement to ensure a robust health and safety management system that can be considered as an example of best practice. Uppermost is the need to review and assess the impact and opportunities of the Agency Transformation. The need for strong leadership for health and safety is a key priority and proposals are offered for training of the Executive Committee (ExCo) and the Board to ensure their understanding of these responsibilities. Further proposals then build on developing a more robust framework based on identifying further opportunities and improvements.

2. Introduction

2.1 The management of health and safety in the organisation has evolved considerably since NIBSC merged with the MHRA in 2013. The merger resulted in the joining of two distinct management systems for health and safety governance. NIBSC has always been reviewed by the Health and Safety Executive (HSE) for its high hazard biological activities and has had a good record for compliance and maintained a good relationship with HSE. The MHRA achieved certification by BSI to Occupational Health and Safety Standard ISO18001 for the office-based activities and the higher risk Inspectorate and Enforcement activities.

2.2 The two systems remained separate for several years until they were joined under the management within NIBSC Operations. It was decided in 2016 that management of the health and safety team and its activities should be moved out of the operating functions to provide more robust and independent governance and it was moved into NIBSC Corporate Affairs in 2017. Whilst still being managed close to the highest risk biocontainment activities at the South Mimms site, this change has provided a more centralised approach to managing health and safety and providing a clearer strategic oversight of requirements for the wider organisation. There have been further organisation changes in the recent Transformation programme that will be discussed in section 2.17.

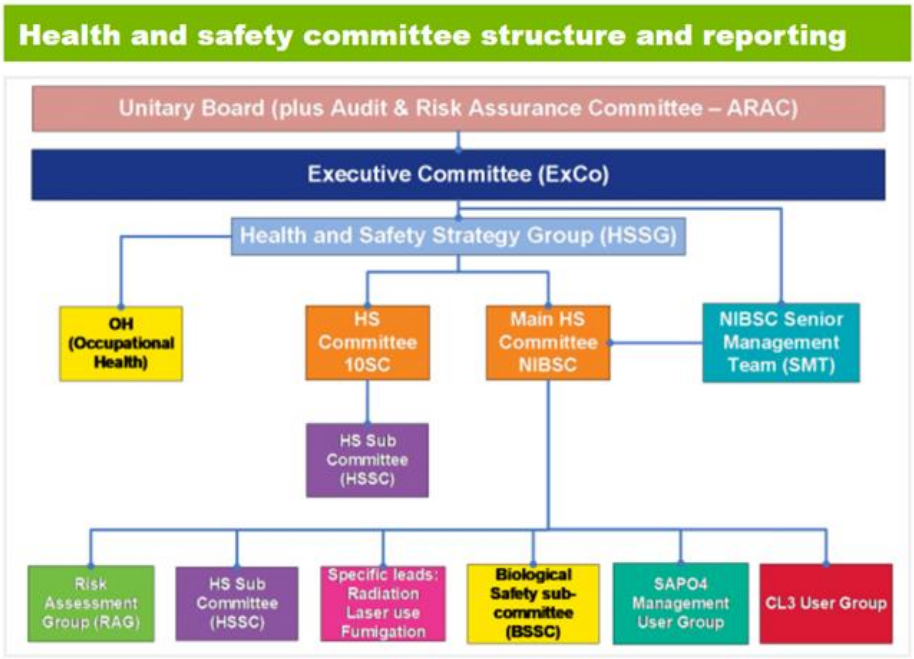
2.3 The best starting point is to define ‘best practice’ in terms of health and safety. The HSE refer to and assess against ‘good practice’ which they use as a generic term for those standards for controlling risk which have been judged and recognised by HSE as satisfying the law when applied to a particular relevant case in an appropriate manner. Further information can be found on the HSE website hse.gov.uk under ‘Risk management: Expert guidance - Good practise’. 'Good practice', as understood and used by HSE, can be distinguished from the term 'best practice' which usually means a standard of risk control above the legal minimum.

2.4 Good practice can come in many forms and vary for different types of organisations. Examples of good practice by other organisations, may not always be suitable for all, but peer review and sharing of good practice can feed into continual improvement, and ultimately provide an understanding of best practice.

2.5 The Agency Health and Safety Policy Statement sets out the requirements to ensure health and safety is a prime responsibility, that there is a duty to comply with all applicable legislation, and that there is committed and effective leadership for continual improvement in a cost effective and structured manner.

2.6 A key challenge for managing health and safety within the Agency is the need to manage distinct types of working for different Groups, with diverse requirements for those staff in different environments. Our health and safety response needs to be proportionate to the level of risk, therefore focussing efforts on where the higher risks are, but not ignoring lower risks. Variation in activities is not unusual so the comparison with similar organisations is an essential part of assessing our performance in line with best practice. Measuring our performance is therefore an essential requirement to monitor how we are performing both from an internal perspective as well as through external review.

2.7 Internal methods of monitoring performance – the Agency needs to have an agreed Health and Safety Strategy, approved by the senior leaders of the organisation. Beneath this an Action Plan sets out how we will meet our strategic aims. This requires regular performance monitoring with robust review and challenge. The Agency provides this through its Health and Safety Committee structure, ensuring oversight by senior committees such as the Health and Safety Strategy Committee to set and monitor the strategy, then main committees to carry out high level monitoring, and then sub-committees obtaining input from advocates on performance, risks, and measuring key performance indicators. The committee structure will need to be reviewed in light of the Transformation and the new Agency structure.

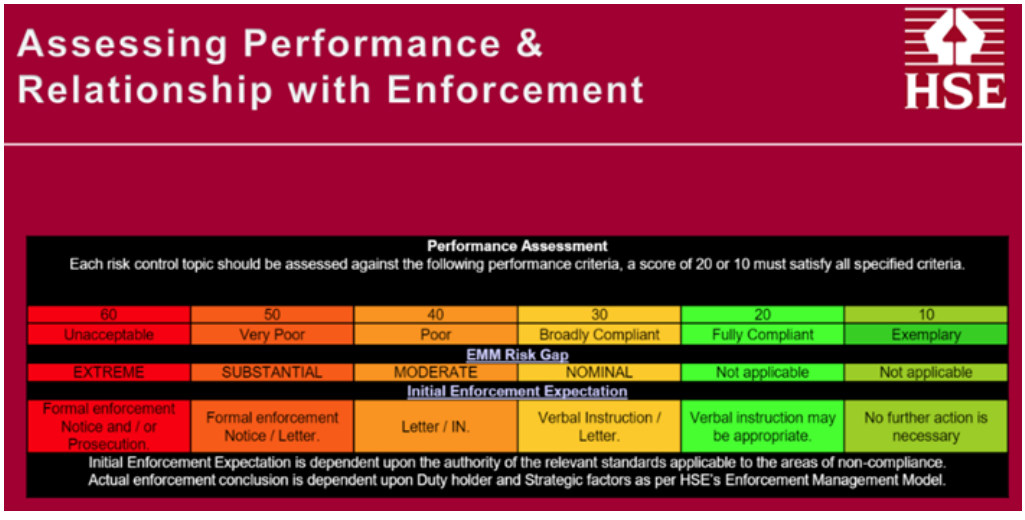


2.8 External opportunities for measuring performance - we learn a great deal from the external assessment bodies that oversee our activities and review our compliance with health and safety legislation and internal and external standards. The Agency has two main assessment bodies covering the different aspects of the work across the organisation.

2.9 BSI provides the external review for the certification under Occupational Health and Safety Standard ISO 45001 (the successor to ISO 18001) which covers the activities of the Agency that have been previously assigned under the Regulator and the Clinical Practice Research Datalink (CPRD). The standard goes beyond the minimum statutory requirements for the Agency activities, but it provides a robust framework to promote best practice and continual improvement of the Occupational Health and Safety management system. The requirements are laid out in the ISO 45001 Management Procedures that outline the need for setting clear objectives, and continually improving to achieve our outcomes.

2.10 What value does ISO 45001 give us? – It is an international standard, demonstrating a mark of excellence and leaders in what we are doing. It is an opportunity to show that we hold the certification and be therefore known by others for demonstrating best practice. We should however be asking ourselves if our customers or our peers know about this, are we using it to our benefit, and what difference does it make. Audits by BSI have shown good compliance, and we are able to show good health and safety systems are in place. They do however suggest that the Agency could be more aspirational in its targets that it sets for health and safety, and these should be at a higher strategic level as well as some of the more detailed tactical requirements.

2.11 The HSE provides the external oversight of our safety management system and operational standards for work with biological agents. The work under this category takes place on the South Mimms site housing the Agency laboratories where the work of the former NIBSC division is carried out. NIBSC has a good relationship with HSE with good cooperative discussion during the annual programme of interventions and at the annual review. We have held a good safety record and where incidents have occurred, there have been no cases of serious injury, and any incidents have been worked through with HSE to address and ensure continued improvement on practices. Due to the nature of the work, NIBSC starts with an inherent risk score of 60 (see diagram below), and its performance to manage the risk has over the years been scored at the higher end with 30 (Broadly Compliant) to 20 (Fully Compliant). We will always strive to meet an Exemplary score of 10, where no further action is necessary, but the diversity of potential risks on the South Mimms site and nature of the work and level of risk makes this almost impossible to achieve, and has been stated by HSE that it has never been issued, and is highly unlikely to be given to an organisation.



Review by HSE is essential to allow us to operate the high hazard laboratory activities at the South Mimms site. Any breach of the requirements carries with it the risk to people and the environment, as well as significant reputational risk. The required level of performance can only be achieved by continuing to invest in the site infrastructure and staffing.

2.12 Examples of feedback from recent intervention visits or investigations include:

- 'Leadership Intervention visit (April 2021) – Positive inspection with helpful discussions regarding the Agency's planned organisational changes, Agreed the Agency's strategy and direction of travel is appropriate, Leadership is a key priority area in the H&S Action Plan for 2021-22 (including high hazard assurance monitoring and training for senior leaders)'
- 'SAPO4 Intervention visit (February 2021) – satisfied overall with the risk controls in place although facility not currently running at SAPO4 level due to works that have been taking place on the laboratories. Update to be provided when ready to work at SAPO4. An action plan will be discussed within NIBSC to strategically plan next stages for this'.
- 'CL3 TB Intervention visit (February 2021) – overall high standard and impressed with the facility. Some suggestions on possible alternative processes discussed. Verbal instruction received - being progressed via H&S Committees'
- 'COVID-secure measures at the South Mimms site (February 2021) - satisfied with all the procedures in place – good documentation, physical measures, training and communication, and good evidence of all the measures and staff following them while they were on site. No concerns raised.'
- SAPO4 positive pressure spike incident Enforcement Letter (March 2021) – requirement to review all pressure controls to reduce risk of containment breach due to sudden positive pressure during fan fail. Adjustments made to rectify, and incident closed. Followed by further improvement programme to update the Hazard and Operability study (HAZOP) and Layers of Protection Analysis (LOPA).
- Laboratory spill investigation and Enforcement Letter (February 2021) – review of process for introduction of new work and review of CL3 emergency spillage procedures. Incident closed.

2.13 Peer review and sharing best practice – one of the most effective ways of comparing against best practice is to work closely with other organisations and through sharing of information (incidents, risk alerts, lessons learnt, collaborative working). The health and safety team and staff representatives are members on many UK committees such as UK Biosafety Leadership Group, Biological Agents Steering Group, UK CL4 (Containment Level 4) group and National Laboratory Alliance, Financial Institutions Safety and Health (Offices H&S contact group), TRIP (Travel, Risk and Incident Prevention) group, IOSH (Institute of Occupational Safety and Health) regional groups and the 10 South Colonnade (10SC) tenants group. Presence on these external groups allows the sharing of best practice across the sector and continued review of health and safety management systems for each of our organisations. Examples of areas reviewed are varied but the Agency has been able to share examples of good practice, and to learn from others to continually improve our systems. This type of peer review is invaluable and relies on open and honest discussion and having the appetite to change and improve where possible.

2.14 Comparing resourcing models of Health and Safety Management – different models exist in how to resource an organisation sufficiently to manage health and safety requirements. There are benefits and risks with each model, and the two most common models are outlined below.

2.15 The structure within the Agency, based on the strategy from its predecessor structures, has been to maintain a small health and safety advisory team, with health and safety staff support roles embedded throughout the organisation in the form of advocates or specialist roles as an addition to their own function. This can have benefits of using staff expertise in their own skill areas to bring knowledge to the management of the requirements. It can also allow closer alignment with embedding the management responsibilities for health and safety across all activities of the organisation. It does however require time and commitment from those staff, including training and maintaining competence on top of their own roles. It also relies heavily on the goodwill of staff to take on the responsibility, ongoing need for additional training for many staff, and instilling a culture of ownership by the staff. It is worth stating that these additional H&S responsibilities for staff are not included in their job descriptions as they are additional activities taken on through interest and good will.

2.16 Converse to the above model is that of having specific dedicated roles within the H&S team to cover the specialisms, with roles such as Biological Safety Officer, Radiation Protection Supervisor, Laboratory Safety Officer, Laser Officer, engineering safety specialists, human factor specialists, as roles within the dedicated team rather than being part of other roles. The result is that a larger health and safety team is required but it provides dedicated skills that can be devoted to the oversight and leadership of these activities. Many organisations (e.g. UK Health Security Agency and Animal & Plant Health Agency) use this model and invest in roles where they have identified the risk and need for expertise. It ensures breadth and knowledge of expertise across the team and defines clearly the health and safety roles in the organisation.

2.17 The model within the Agency has been a stable set-up on the whole and has been cited as a good model by external reviewers. The recent Agency Transformation has resulted however in a risk that now needs to be closely managed. Following the consultation around the Agency Transformation, the H&S team has been mapped to the Science, Research and Innovation Group that has responsibility for the scientific functions on the South Mimms site. However, many staff within the organisation that held roles as advocates and specialists have changed role, and therefore there are temporary gaps in the health and safety staff support infrastructure, and this could result in a risk to the health and safety compliance of the organisation.

2.18 The H&S team are monitoring the risk as the structure evolves to identify where there are gaps that might carry risk. This monitoring is being also closely reviewed and discussed through the health and safety committees, including with Trade Union Staff representatives, who all provide valuable support and input to the health and safety management system.

2.19 In the area of laboratory safety, the health and safety team are already aware of staff changes that will require steps to strengthen laser safety, chemical safety and improve resilience in the safe use of certain high-end laboratory equipment. This process is at a very early stage of understanding the impact and the next stage is to map out competencies and assess the gaps. The range of health and safety requirements at South Mimms is extensive, and we anticipate a significant training programme to ensure a sufficient diversity of staff with the necessary skills. This training will be in addition to a known training need where the effects of the COVID-19 pandemic have resulted in a delay in being able to deliver some of the regular training programmes. The training requirement will be greater in financial year 2022-2023 than in previous years and the cost of this will need to be managed closely by the health and safety team, with a commitment by Senior Management to review the additional costs identified.

2.20 The Transformation does also bring new opportunities in how health and safety is managed across the wider organisation. Working as 'One Agency' brings together workstreams that are already in place but can be built on within a new Agency culture. The Health and Safety team and Human Resources team already work closely together in areas such as Occupational Health (OH) and Wellbeing, monitoring the external OH contract delivery together. In addition, the COVID-19 pandemic has resulted in close working on managing the staff requirements for working in different locations, and the model of current working and possible hybrid working models for the future are being reviewed for the various work locations such as home, 10SC, South Mimms and travelling/on the road. The need for clear policies and support for staff when working off site in the UK and overseas is also being managed through close working between Health and Safety and HR.

3. Proposal

3.1 The background above provides an explanation of best practice and how we can assess our H&S performance. Through those methods of assessment, we can identify steps to take that enable us to act on the areas where we can see a need for immediate action and where there is scope for improvement. They are listed in a suggested order of priority.

3.1.1 The Transformation of the 'One Agency' does now present an opportunity to really develop the health and safety culture. The impacts of the changes and new risks will be significant, but the assessment of these allows us to fully review roles and responsibilities, committee structures and governance processes. This will help to implement improvements and possible streamlining of processes. This will take some time to address but it is the most critical after such a fundamental change to the organisation and it will be included in the Health and Safety Action Plan for 2022/23. The HSE have provided information on assessing human factors during organisational change and this will be used to assess and manage issues. There will need to be a mechanism for escalating risks and gaps as they become clearer through the work to embed the new organisation following Transformation.

3.1.2 Visible H&S Leadership is essential in any organisation and strengthening H&S knowledge among the leadership is an action on the H&S Action Plan. If the Board supports this request, then appropriate training will be developed and the most appropriate training incorporated in the Board's Schedule of Business.

3.1.3 With a new structure now in place, there will be a need to review the benefits of existing BSI certification and assess the scope for the new organisation. The previous distinction of the 10SC site is no longer as clear and there could be consideration for narrowing the scope to be proportionate with the risk areas (e.g. Inspectorate, Enforcement and overseas travel). Certification could be limited, whilst the rest of the Agency works in alignment to the framework of the standard and we propose the impact of this should be explored.

3.1.4 The naming of the new Health & Safety and Quality Assurance function within Science Research and Innovation helps it to be a focussed and clearly labelled team and therefore clear to stakeholders where the health and safety activities are managed. The clearer combination with Quality Assurance also gives a greater opportunity to explore synergies between health and safety and quality. Work will commence by the new team to review more joined up ways of working, and to share best practice from each area, and we propose ensuring that there is cross-Agency discussion with all relevant Groups to ensure input and engagement for developing these new opportunities and improvements.

3.1.5 Building a new robust Health and Safety Management System will be a balance of costs and resource, and the ultimate aim is to ensure the safety and wellbeing of our staff and be able to demonstrate excellence. This will require a strong commitment from Agency leaders, and through every Group of the new organisation. We will need to work closely in some areas to further develop existing joint aspects, such as with Human Resources to manage the Occupational Health provision, and to ensure H&S and Wellbeing activities are developed together. In addition, specific activities of the organisation will need to be reviewed with respective Groups to identify any additional resource required for these activities. An example of the higher risk travel destinations required by staff in Inspectorate and Enforcement roles, and for some other roles in the organisation.

3.1.6 The Agency Health and Safety policy statement and draft strategy recognise health and safety for staff being a key priority and this paper recommends increasing the profile of this priority both internally and externally. Examples of best practice in external promotion can be seen for universities such as Imperial College and University College London and it is proposed that the Agency looks at other external benchmarks when it reviews and updates its public statements on its health and safety policy.

3.1.7 The H&S Strategy has been in draft form over the last few years and used as the basis for the annual H&S Action Plan. It is reviewed via the Health & Safety Strategy Group (HSSG) but good practice is for it to be subject to Board level approval and oversight.

The approved strategy should then be publicised to staff in the context of the wider promotion of health and safety management across the Agency. It is proposed that the Board reviews the progress of the Agency Health & Safety Strategy in its Schedule of Business, and that a regular 6-monthly programme is scheduled by ExCo for receiving updates on how the Agency is performing against its Health & Safety Strategy, action plan, key performance indicators, and its biocontainment safety performance indicators.

3.2 These proposals aim to put in place a programme to build on existing good practice and commit to the requirement for continual improvement to ensure a robust H&S management system that can be considered as an example of best practice.

4. Recommendation

4.1 The Board is asked to include Health & Safety Leadership training into its Schedule of Business with an external trainer. If this is agreed, work will commence to make these arrangements, plan the scope of the training, and develop an annual refresher programme.

4.4 The Board is asked to include regular Health & Safety reports into its Schedule of Business to gain assurance on how the Agency is performing against its Health & Safety Strategy, action plan, key performance indicators, and its biocontainment safety performance indicators. The Health & Safety Strategy will be finalised and approved by the Health & Safety Strategy Group and Executive Committee, before for endorsement by the Board, so that this reporting cycle can begin.

Dr Marc Bailey
February 2022

Medicines & Healthcare products Regulatory Agency

BOARD MEETING HELD IN PUBLIC

15 February 2022

Title	What assurance can be provided by Organisational Development and Change Committee?
Board Sponsor	Amanda Calvert
Purpose of Paper	Assurance

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

1. Introduction

1.1 The Organisation Development and Remuneration Committee (ODRC) met on 7th February 2022. The agenda for the meeting covered:

- ODRC Role and Terms of Reference
- A review of the services that will be provided by the Agency and priorities for establishing them in the new Agency operating model
- A review of the Board's input on leadership from December 2021 and how to develop and deliver an effective leadership development programme to staff most effectively.
- A review of the results on effectiveness of senior leadership culture from the balanced scorecard

2. Executive Summary

2.1 Role of ODRC

2.1.1 The Terms of Reference for the Committee were reviewed.

2.2 Agency Transformation

2.2.1 Significant progress has been made with the new chief officers and their teams to define 23 core services that will enable the Agency to deliver its future operating model. The committee recognised that this work has taken a long time and would have ideally been delivered last year.

2.2.2 The work has defined services that are both key to maintaining core competence to operate as a regulator and those that are innovative and will create future competitiveness.

2.2.3 The committee stressed the importance of defining and implementing the services rapidly and to work closely with the financial and HR teams to ensure that there will be funding and people with the right capability and skills to deliver these services in a sustained way.

2.2.4 The committee requested an update on the services following engagement with the relevant service users with the aim of co-design as appropriate.

2.3 Leadership Development Programme

2.3.1 The committee recognised that there has been significant progress in the work to define and deliver a plan that will strengthen the leadership capability at all levels within the Agency. The Board can be assured that their steers from the December seminar have been incorporated into the plan by the team.

2.3.2 Whilst HR are leading on the development of the leadership development programme, the committee were assured that this is a programme of work that is owned by all the chief officers. The committee recommended that the role of HR was made more explicit.

2.3.3 It is recognised that actions speak louder than words and that all senior leaders, especially the Board and executive officers need to role model the behaviours and values of the Agency.

2.3.4 The proposed leadership development plan comprises six goals that recognise the challenges that such programmes have faced in the past where leadership capability has often been seen as secondary in importance to technical expertise. In the new programme there is recognition that technical and leadership capabilities are equally important, especially for more senior roles.

2.3.5 The Board and committee have been asked to support the team through mentoring and sharing their experiences.

2.3.6 A plan has been developed that addresses the following aspects: setting leadership expectations, creating an environment conducive to leadership development, developing leadership capability and assessing leadership performance.

2.3.7 The committee will continue to review progress against the implementation plan, both in terms of metrics, success stories and areas of challenge where additional support is required.

2.4 Senior Leadership Culture and Balanced Scorecard

2.4.1 The results of the internal audit review of culture that indicated limited assurance was discussed and will be revisited at the next meeting to review progress against recommendations.

2.4.2 In line with the internal audit recommendations to have improved governance, clear responsibilities and timelines for actions, the committee will continue to monitor the progress of actions in the culture improvement plan.

2.4.3 The culture metrics in the balanced scorecard pinpoint just two of the cultural challenges for the Agency; “leaders walking the talk” and “taking timely decisions”. However, the committee were assured that the Culture Action Plan (CAP) outlines a broader programme of work for implementation across the Agency.

3. Establishing the services that support the future operating model for the Agency

3.1 The committee reviewed the work that had been undertaken to establish the core services that the Agency will establish to deliver the strategy and objectives. It was noted that ideally this work would have been progressed in 2021.

3.2 Twenty-three services have been identified and six have been prioritised for implementation as soon as possible. The process to identify the services has been led by the chief officers and their teams and are aligned to the “Moments of Value” which deliver the services most valued by patients, healthcare providers, researchers, industry and other stakeholders.

3.3 Small cross agency “Tiger-Teams” are working to optimise the six priority services and are challenging themselves to think innovatively to think about regulation from end-to-end, by leveraging new technology and partnerships to deliver value for patients. The committee were encouraged to see that there was good evidence of cross-functional working and collaboration in these teams.

3.4 The committee encouraged the teams to work closely with the Finance and HR teams to ensure that the solutions were both affordable and that the people were trained and supported to deliver these new ways of working.

3.5 The committee will continue to monitor progress especially with regard to integration with financial planning work on fees and spending review as well as the development of the people strategy and workforce planning. The committee also endorsed receiving a further update following engagement with relevant service users at an appropriate point in the service development.

4. Leadership Development Plan

4.1 After several iterations the leadership development plan is now aligned to deliver the changes in leadership culture that are required to deliver the new strategy. There is a very close alignment with the work on culture and the two areas are inextricably linked.

4.2 The committee commended the team on the work that had been done to develop the new plan that will encourage staff at all levels to develop and apply their leadership capabilities.

4.3 There is a need for a clear set of leadership expectations and the committee agreed that the Agency Values and Behaviours which are currently being reviewed along with the Civil Service Leadership in Action Attributes provide a foundation to build from. The Board will be invited to contribute to the refreshed Values and Behaviours Framework, but this should not delay progress with delivery of the plan.

4.4 The committee were very supportive that the equality, diversity and inclusion (EDI) principles permeate the plan and become integral to the leadership style and behaviours demonstrated by Agency staff. The committee also welcomed the alignment with the work being done by the Talent and Capabilities Team to ensure that there is conscious inclusion to develop a diverse set of leaders across the organisation.

4.5 The role of the Board and ExCo was discussed, and it was emphasised that senior leaders need to role model leadership expectations, address poor leadership behaviours and champion the importance of the leadership agenda. This is particularly important in areas where leadership and cultural development is seen to be of secondary importance to technical skill. Both capabilities are essential.

4.6 The committee was very supportive of plans to extend mentoring and reverse mentoring, using stories and lived experiences to communicate what leadership means and the impact it can have. In addition, opportunities to meet more junior staff and encouraging them to attend Board meetings were welcomed.

4.7 The committee emphasised the importance of bringing leadership capability to life with stories, as well as metrics, the importance of mentoring and coaching at all levels and to ensure that everyone has a personalised leadership development goals appropriate to their own role and development needs.

5. Effectiveness of Senior Leadership Culture

5.1 It was recognised that the low scores for leadership effectiveness from recent surveys for leaders “walking the talk” and “taking timely decisions” needed to improve. The committee agreed that these scores were symptomatic of the need for cultural change across the organisation. There had been an effective deep dive and diagnosis into the cultural drivers causing some of the behaviours that were driving these scores. This was recognised by the committee and the internal auditors.

5.2 A cultural action plan has been developed that outlines specific actions that senior leaders can take, and this plan is closely aligned to the leadership development plan. It was recognised that leadership behaviour has a big impact on the culture of any organisation. The committee and internal audit identified that the implementation of the framework needs to be underpinned by a strong governance framework and clear actions, timelines and responsibilities. The progress will continue to be reviewed by the committee.

5.3 The committee recognised that this was a long-term commitment, and it is tough to change the culture which is shaped essentially, by new ways of interacting with each other. The challenges of working remotely for two years were recognised. The culture action plan, the leadership development plan, proposals to improve the culture metrics and the organisational transformation are cornerstones for delivering the cultural shift required. The committee offered support and experience to the team and progress will continue to be monitored both through review of metrics and using stories to demonstrate success.

6. Forward Plan

6.1 The committee will continue to monitor the progress of the work on services, culture and leadership development.

6.2 For the next meeting it was proposed to review how the work on equality, diversity and inclusion is progressing and how it is being integrated into the leadership and culture development programmes.

Amanda Calvert
ODRC Chair
February 2022

Medicines & Healthcare products Regulatory Agency

BOARD MEETING HELD IN PUBLIC

15 February 2021

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

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

1. Executive Summary

1.1 The Audit and Risk Assurance Committee (ARAC) met on 25 January. The Committee was pleased to welcome Claire Harrison, Chief Technology Officer and Rose Braithwaite, Deputy Director of Finance to their first ARAC meeting as standing attendees.

1.2 A joint meeting with the Patient Engagement and Safety Committee (PESC) also took place on 2 February to agree how the two Committees can best work together to provide assurance to the Board on the development, governance and data standards of SafetyConnect.

1.3 The Board assigned three actions to ARAC on which we reported to the Board in November but given their critical importance to the performance of the MHRA we reviewed progress at our January meeting.

2. Action: Financial sustainability - ARAC to review the Agency's likely financial performance for the remainder of 2021/22 together with the cost-effective utilisation of the Agency's reserves.

2.1 The projected financial position for 31 March 2022 remains broadly the same as reported to the Board in November but the level of financial reserves which will have to be surrendered to the Department of Health once the Agency ceases to be a Trading Fund remain uncertain. Good progress with the redundancy programme means that the associated costs which can be funded from reserves is now more precise. However, uncertainty remains over how much of the financial reserves can now be used to fund essential digital projects in the remaining two months of 2021/22. This means that a higher level of critical digital expenditure will need to be incurred in the next two years which the Agency will have to find new ways of funding.

2.2 We revisited the risks inherent in the MHRA's "most likely outcome model" which is intended to provide a best estimate of income and expenditure over the next two to three years. We were assured that there is sufficiently comprehensive information to support reliable financial planning. The launch of the MHRA's new operating model on 10 January was a significant achievement meaning that the Agency is better able to determine more accurately its ongoing running costs. A number of critical income and expenditure planning assumptions do now need greater precision and further challenge. These include:

- digital investment (the new Chief Technology Officer is revalidating the Agency's Digital Road Map);
- fees and charges (while Finance has work underway there needs to be a clear, transparent and precise timeline when the new fee structure will be in place);

- organisational structure (the Agency's modelling refers to potential further realignment and skills enhancement but more clarity is needed on this and how it will be funded); and
- corporate overheads (good work has been done, particularly in accommodation savings, but greater efficiencies are likely to be needed).

2.3 We were assured that the Agency has a reliable budgeting and business planning process for 2022/23. We discussed the budgetary and management cost information routinely available to the Executive Team and managers to take decisions and review performance. Finance are working to improve the quality of cost information. A new chart of accounts is being introduced to enable this and we were told that this would be done by the beginning of the next financial year. We will secure further assurance on the quality of management information through the work of Internal Audit in 2022/23.

3. Action: Review and consider a higher risk rating on the implementation of the Future Operating Model.

3.1 This was covered as part of the corporate risk register review. See sections 5.2.3.

4. Action: Review and seek assurance on the risk in relation to Digital Implementation.

4.1 This was covered as part of the corporate risk register review. See sections 5.2.4.

5. Other issues covered by the Committee

5.1 **Preparation for change in Trading Fund status**

5.1.1 We received the Agency's plan for managing the transition from Trading Fund status at our November meeting and asked Internal Audit to undertake a review so that we could obtain independent assurance at our January meeting that implementation of the plan was on target and that risks were being appropriately managed. Progress has been slower than planned and as a consequence it has not yet been possible for Internal Audit to complete its review.

5.1.2 Finance provided a paper setting out the actions taken to date and planned, but accept that preparation for the change in status has been slower than they would have liked. A cross-Agency Project Board should be in place from February with dedicated professional resource. Risks to successful transition have nevertheless increased because of the short time remaining until 31 March 2022. Sustained senior leadership of this transition is now needed to manage this risk. The first six months of 2022/23 will be critical as managers and their teams have to get used to the more detailed reporting to the Department, which the change in trading fund status will necessitate. This will need enhanced financial systems and these must be supported by cultural change This requires concerted focus as a cross- Agency responsibility and not just by Finance.

5.2 **Risk Management**

5.2.1 We reviewed the risk register and were assured that this is comprehensive and covers the key risks which the MHRA currently faces. In keeping with good practice, we support the Agency's intention to refresh the register in the Spring. We noted that in spite of some well-focused controls and mitigating actions, the overall status of most risks remained unchanged. We were told that this was because many of the actions and controls were planned or in the process of being implemented and there was not yet sufficient evidence to demonstrate their impact on the relevant risk to justify any change. We encourage the Agency where practicable to accelerate this process so that resources can be prioritised on those risks which are inherently much more difficult to mitigate.

5.2.2 To enhance the assurance we can provide to the Board, the Committee reviewed progress in mitigating the adverse impact of two critically important internal risks: implementation of the new operating model; and digital implementation.

Future Operating Model

5.2.3 The Agency's new operating structure went live on 10 January and we were assured that the Agency is on target to have filled or offered contracts to the top three tiers in the new structure. We are encouraged by this good progress. Work is now underway or planned on key system design. ARAC recognised the importance of this work but commented that it required focus and consolidation as not every system or process will require fundamental redesign. It is important that resources are deployed where they are most likely to add most value.

Digital implementation

5.2.4 The Agency has met the necessary internal and external scrutiny thresholds and will shortly award a contract for a new digital supplier. This is an important development in the implementation of the digital strategy. We were given assurance that new contract was designed to ensure that the Agency secured ongoing value for money and that there was sufficient flexibility to allow the Agency to respond to new requirements or future advances in technology. We were also assured that the Agency would be strengthening its commercially experienced staff and skills to manage the supplier. The Chief Technology Officer is now reviewing the current Digital Road Map which will be re-presented to the Board. We support this but agree that digital transformation remains a significant risk for the Agency in terms of its importance to the efficient and effective delivery of the Agency's regulatory responsibilities and its affordability. We have asked Internal Audit to review the management of the contract with the new digital supplier as part of its 2022/23 programme. The Organisation Development and Remuneration Committee (ODRC) and ARAC have agreed to hold joint meetings in 2022/23 to provide assurance to the Board from their complementary remits on progress with the Digital Road Map.

5.3 **External Audit**

5.3.1 The National Audit Office (NAO) supported by KPMG presented their plan for the audit of the Agency's financial statements for 2021/22. We discussed and agreed external audit's assessment of the Agency's key risks and their approach to securing the evidence which the Comptroller and Auditor (C&AG) will need to provide his audit opinion. We agreed the audit fee and gave the assurances on behalf of the Agency which the NAO routinely requires from Audit Committees.

5.3.2 We received and agreed a paper provided by the new Deputy Director of Finance on the accounting policies which will apply to the MHRA's financial statements for 2021/22.

5.4 **Annual Report Timetable 2022/21**

5.4.1 At our November meeting we considered a comprehensive paper from Finance on lessons learned from the preparation of last year's Annual Report and financial statements. Drawing on this, the Agency has prepared a detailed plan for this year's timetable. An important change which ARAC fully supports is that the Governance Office will take overall responsibility for the preparation of the Annual Report. The Board will be asked to approve the Annual Report including the Financial Statements at its meeting on 21 June. ARAC has included some contingency in its timetable to resolve any outstanding issues after 21 June to help ensure that the MHRA meets the statutory requirement to lay its Annual Report in Parliament before the Summer Recess.

5.5 **Internal Audit**

5.5.1 The original intention was that ARAC would consider four Internal Audit Reports: Cash Management (requested by the Agency); Progress in Implementing the Recommendations of the Independent Medicines and Medical Devices Safety Review; Transition from Trading Fund Status; and Organisational Culture. Of these, only the last one had been agreed by the Agency (discussed in paragraph 5.5.2) at the time of our meeting. The Committee recognises the considerable pressure on management time at present, but as a general principle it is good practice that Internal Audit's reports are responded to promptly to provide the necessary assurance to the Committee. ARAC has agreed to hold an additional meeting on 7 March to consider the three outstanding internal audit reports.

5.5.2 In addition, Internal Audit has two other reviews under way: SafetyConnect and the Innovative Licensing Access Pathway (ILAP) and a third is being scoped on Corporate Governance. We received assurance that, provided all of this work is completed, the findings responded to promptly by the Agency and formal reports reviewed by ARAC, Internal Audit would be able to give its annual assurance for 2021/22 to Dr Raine as Accounting Officer.

5.5.3 Internal Audit gave a limited assessment for its review of the Agency's management of its Organisation Culture Change programme. The key reason for this was that, at the time of Internal Audit field work in November, the Agency was unable to demonstrate that it had a structured plan of supporting actions and associated metrics to track progress. The Agency has accepted all of the Internal Audit recommendations and assured the Committee that securing successful cultural change would receive increased priority now the new Operating Model has been launched. The Organisation Development and Remuneration Committee has agreed to draw on Internal Audit's work in continuing to seek assurance on progress in achieving the cultural change required by the Agency.

5.6 **Human Resource Controls**

5.6.1 In 2020, in response to a number of over and under payments to Non-Executive Directors, Internal Audit at the request of ARAC undertook a review of the Agency's overall approach to supporting Non-Executives, including remuneration. As a result, the Agency enhanced its controls and support for Non-Executives. In December 2021, the Chair of ARAC was alerted to ongoing payments to a Non-Executive Director who had completed their term of office. In addition, there were a number of instances concerning the reconciliation or appropriateness of pay roll data used in strategic decision making. In response, the Committee discussed these issues with the Head of Human Resources and Finance.

5.6.2 In respect of the overpayment, we were given assurance that this had happened because the external payroll provider had not actioned an instruction from HR. Going forward, we were told that HR would seek confirmation that such instructions were actioned. Concerning the reconciliation of payroll data and ensuring that appropriate and accurate staffing costs were used for decision-making, HR and Finance said that in future they would ensure that more attention was paid to understanding the business decision under consideration so that the relevant staff costs were provided. The Committee welcomed these assurances but asked HR to provide a paper for our next meeting which set out the controls it had in place.

5.7 **Safety Connect**

5.7.1 On 2 February, ARAC and the Patient Engagement and Safety Committee held a joint meeting to consider how both Committees could secure ongoing assurance from their different perspectives on the implementation of SafetyConnect and the realisation of its intended benefits for patients.

5.7.2 SafetyConnect is a strategically important programme for the Agency, as once fully implemented it should significantly enhance the completeness and quality of data available to help ensure patient safety. The programme consists of five projects and we received a presentation on how these are being managed. We were pleased to note how key internal personnel are being brought together as part of the Agency's new structure to manage the interdependencies in the programme and to promote strong governance.

5.7.3 The risk register is comprehensive and there are a number of key risks associated with:

- the successful implementation of the new technology and its integration with the Agency's common data platform;
- the scale of data transfer required;
- the interoperability of SafetyConnect across the NHS and industry through the application of common standards to maximise the completeness and usability of data, particularly in being able to track patient outcomes; and
- in maintaining ongoing patient trust and confidence.

The Agency recognises that these risks require careful management. Some delay in the programme means that more development expenditure than originally planned will be incurred in 2022/23.

5.7.4 Patient engagement to date is encouraging and we made a number of suggestions as to how this might be further enhanced including the digital design of the Yellow Card, maintaining patient confidentiality and other representative groups to consult.

5.7.5 We very much support the ambition which the Agency has for SafetyConnect not only in enhancing patient safety but the wider contribution which it could make to public health. We suggested that at some point once the programme is more advanced, it would be beneficial to have a longer term strategy for SafetyConnect which considers the opportunities and potential wider benefits both nationally and internationally.

5.7.6 Our experience in holding periodic joint Committee meetings on issues of relevance to our respective remits is positive. This is because assurance is strengthened through the synergy and added value which combining different perspectives brings and also in the better use of executive time. When appropriate, we will continue this approach to enhance assurance to the Board.

Michael Whitehouse
Chair ARAC
February 2022