Medicines & Healthcare products Regulatory Agency

AGENDA FOR BOARD MEETING HELD IN PUBLIC

10:00 – 12:30 on Tuesday 20 July 2021

Chair: Stephen Lightfoot

	AGENDA ITEM	**PURPOSE**	**PRESENTER**
10:00	INTRODUCTION		
	1. What are the priorities for this meeting and how will the meeting run?	Information	Chair
	2. Are there any Apologies or new Declarations of Interest?	Information	All
	3. What were the minutes and actions from the last meeting?	Approval	Chair
	CURRENT CONTEXT		
10:15	4. What are the current key issues from the CEO's point of view?	Discussion	June Raine
10:35	5. What is the current performance of the MHRA on the Balanced Scorecard?	Assurance	Jon Fundrey
	PATIENT SAFETY		
10:50	6. What progress is being made on the short, medium and long-term deliverables from the Cumberlege Review and how is their impact being measured?	Assurance	June Raine, and Mercy Jeyasingham
	DYNAMIC ORGANISATION		
11:10	7. What assurance can be provided by Organisational Development & Remuneration Committee?	Assurance	Anne-Toni Rodgers
11:25	8. What are the strategic priorities for the development of culture and diversity to enable the Future Operating Model?	Strategic Direction	Jon Fundrey
	FINANCIAL SUSTAINABILITY		
11:45	9. What assurance can be provided by the Audit & Risk Assurance Committee?	Assurance	Michael Whitehouse
	EXTERNAL PERSPECTIVE		
12:00	10. What questions do members of the public have for the MHRA Board?	-	Chair
12:30	CLOSE OF MEETING	-	Chair

Medicines and Healthcare products Regulatory Agency

Minutes of the Board Meeting Held in Public of 15th June 2021

(10:00 – 12:30)

By Zoom Webinar

Present:

The Board

Stephen Lightfoot	Chair
Professor David Webb CBE	Deputy Chair
Dr June Raine CBE	Chief Executive
Dr Samantha Atkinson	Interim Chief Quality and Access Officer
Amanda Calvert	Non-Executive Director
Professor Bruce Campbell	Non-Executive Director
Jon Fundrey	Chief Operating Officer
Mercy Jeyasingham MBE	Non-Executive Director
John Quinn	Interim Chief Technology Officer
Dr Christian Schneider	Interim Chief Science Officer
Michael Whitehouse OBE	Non-Executive Director

Others in attendance

Carly McGurry	Director of Governance
Rachel Bosworth	Director of Communications
Natalie Richards	Secretary to the Board and Head of Directorate
Jude Thompson	Executive Assistant to the Chair

Department of Health and Social Care (DHSC)

Kathryn Glover	Deputy Director, Medicines Regulation and Prescribing, DHSC

Devolved Administrations

Professor Alison Strath	Interim Chief Pharmaceutical Officer for Scotland

Item 1: Introduction

What are the priorities for this meeting and how will the meeting run?

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 a range of patient groups, other health bodies, staff and industry.

Item 2: Are there any Apologies or Declarations of Interest

2.1 Apologies were received from Dr Barbara Bannister and Anne-Toni Rodgers, Non-Executive Directors; Fleur Ruda, Deputy Director of the MHRA, Medicines & Pharmacy division at Government Legal Department; Cathy Harrison, Chief Pharmaceutical Officer for Northern Ireland; and Greig Chalmers, Head of Medicines Policy Branch at the Scottish Government.

2.2 There were no Declarations of Interest.

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.

3.2 The Board noted that the Balanced Scorecard was not yet developed to a suitable standard to report in the month of June, but it will be used to measure Agency performance from July 2021 onwards.

Action 37: Start using the Balanced Scorecard to measure Agency performance
Jon Fundrey

FINANCIAL SUSTAINABILITY

Item 4: What were the financial results of the MHRA in 2020/21?

4.1 The Board considered the MHRA financial performance in 2020/21 as set out in the draft 2020/21 Annual Report and Accounts. These draft results were still subject to final audit sign-off and showed that the Agency had made a net loss of £14.8 million in the year. These draft results had been considered by the Audit and Risk Assurance Committee (ARAC) in advance of the Board meeting; the ARAC Chair Michael Whitehouse updated Board colleagues on some of the notable points from the accounts. In particular, ARAC had questioned the apparent lack of impact of Covid-19 on the financial results given the Agency's huge contribution to the pandemic. Executives explained that cost savings had been made elsewhere, notably on travel, to compensate for the additional £900,000 costs on Covid-19. A further question had been raised with regards to NISBC financial reporting; again the ARAC were assured there were reasonable explanations for this.

4.2 The loss of the Agency's trading fund status on 31 March 2022 was noted; the Board acknowledged that a going concern statement was in place as required by the auditors. The ARAC Chair was satisfied that there were no fundamental issues preventing the accounts being approved in principle; and noted that the MHRA had been through a difficult year and had performed well given the circumstances. It was noted that there are lessons to be learnt about the production of the annual report and work is ongoing with external auditors to build on this experience. The Board commended Boryana Stambolova for her work on finalising the accounts as Deputy Director of Finance before leaving the Agency.

4.3 The Board provided comments on the accounts covering the importance of accurately capturing the costs from the Covid-19 pandemic and ensuring this is described appropriately in the annual report. Further questions were raised on the constituents of the other trading activities in the budget and the programme of work to reduce the deficit.

4.4. Questions were also raised on the accounting for CPRD and it was agreed that a briefing will be held for any Board Directors who wish to increase their understanding of the specific accounting requirements for CPRD.

Action 41: Hold briefing for any Board Directors who wish to understand and reconcile the details of CPRD accounting.

Jon Fundrey

4.5 The Board approved the 2020/21 financial accounts in principle in the knowledge that a VAT issue still has to be resolved with the Treasury and that the external audit still has to be completed. The Board delegated authority to the ARAC Chair to clear the final accounts for the Chief Executive to sign after the final audit issues have been resolved. The Board will require a written note to confirm this has been completed with assurance that the final accounts are not materially different from those considered by the Board on 15th June.

Action 42: The Board approved the 2020/21 financial accounts in principle and delegated responsibility to the ARAC Chair to clear the final accounts for the Chief Executive to sign after the audit issues have been resolved. A written note should be provided to the Board to confirm this has been completed with assurance that the final accounts are not materially different from those considered by the Board.

Michael Whitehouse

GOVERNANCE

Item 5: How well does the draft text of the Annual Report reflect the performance of the MHRA in 2020/21?

5.1 The Board considered the draft text of the Annual Report for the year 2020/21 and provided comments. ARAC had reviewed the Governance Statement contained within the Annual Report and the Board noted that ARAC had concluded that there are no fundamental issues with regards to compliance within the Governance Statement. The Board asked the CEO and Director of Governance to present a revised assurance and governance framework for the new MHRA organisation before the end of the current financial year.

Action 43: A revised assurance and governance framework for the new MHRA organisation should be presented to the Board.

Carly McGurry

5.2 The Board considered the draft text of the annual report and provided comments covering the additional points which could be added in relation to the Agency's engagement with patients and response to the Cumberlege Review; improving leadership and culture; the implications of limited assurance from auditors; and ensuring a short summary of the report is available for stakeholders.

Action 44: The Board approved the 2020/21 Annual Report in principle and delegated responsibility to the ARAC Chair to clear the final wording of the governance statement for the Chief Executive to sign after the audit issues have been resolved. A written note should be provided to the Board to confirm this has been completed with assurance that the final report is not materially different from the draft reviewed by the Board.

Michael Whitehouse

Action 45: The Board were asked to provide any final typographical or wording comments on the Annual Report to Rachel Bosworth by 16 June.

All Board members

CURRENT CONTEXT

Item 6: What are the current key issues from the CEO's point of view

6.1 Dr June Raine presented the Chief Executive's monthly report, which covered topics within the four strategic priorities: (i) healthcare access – including updates on Covid-19 vaccines and vaccine independent batch testing by NISBC; the Rapid C-19 Oversight Group; a novel Polio vaccine; the Innovative Licensing and Access Pathway (ILAP); and the Clinical Trials strategy; collaboration with the Singapore Health Sciences Authority; updates on a new Multi-Agency Advisory Service; the ACCESS Consortium (a coalition of the regulatory authorities for Australia, Canada, Switzerland, Singapore and UK); FDA Project Orbis; a Clinical Trials workshop with the Chinese medicines regulator; and collaboration with WHO for pharmacopoeial monographs for Favipiravir; (ii) patient safety – including updates on Covid-19 vaccines safety; Covid-19 testing; isotretinoin; NIBSC surveillance of SARS-CoV-2 variants of concern; devices sterilisation services; medical devices registration; and Operation Pangaea; (iii) dynamic organisation – including updates on the Agency transformation programme, and Health and Safety Reviews; and (iv) financial sustainability – including updates on corporate overheads and the future fees strategy.

6.2 Dr Raine highlighted that the Agency had a pivotal role at the G7 Health Summit on vaccine confidence and the development of proposals on international trials collaboration. NIBSC completed the testing and certification of 15 batches of Covid-19 vaccine, equivalent to over 14 million doses in the last month, and have now certified the equivalent of over 82 million doses since December 2020. The activity of the MHRA's Communications division must be commended through the pandemic. The RECOVERY trial has been vital to the UK's response to the pandemic and the new Multi-Agency Advisory Service is being established to support the development and adoption of artificial intelligence and data-driven technologies in healthcare. Dr Raine noted that safety remains the Agency's number one priority and there are a number of initiatives to better engage patients and stakeholders in the Agency's work.

6.3 The Board thanked Dr Raine for her report and provided comments regarding how the ILAP patient reference group will be reviewed at the Patient Safety and Engagement Committee to seek assurance on progress and meaningful dialogue with patients; ensuring innovative smartphone technologies are utilised appropriately particularly in relation to clinical trials; common data standards and work-sharing agreements; and the impact of EU Exit on the Agency's Inspection and Enforcement activities. The Board noted Dr Raine's report with thanks.

HEALTHCARE ACCESS

Item 7: What are the strategic priorities for the development of the Innovative Licencing & Access Pathway?

7.1 The Board considered a paper defining the strategic priorities for the development of the Innovative Licensing & Access Pathway (ILAP). The Board noted that this new ambitious pathway for accelerating and reducing the time to market for innovative medicines was launched in the UK in December 2020 and has been open for business

since 1st January 2021. The ILAP provides a unique framework for enhanced collaboration between the MHRA and the two ILAP partners, the National Institute for Health and Care Excellence (NICE) and the Scottish Medicines Consortium (SMC), and supports expedited, efficient and innovative approaches to the product development programme – including iterative assessments, proactive pharmacovigilance and a whole-lifecycle approach to efficient evidence generation.

7.2 The Board reviewed the update of the ILAP activity to date and its proposed future development as the principles and operational aspects continue to evolve. Professor Strath commented that the SMC is incredibly supportive of this vital work and the benefits of early-stage discussion with companies cannot be overstated. The Board provided comments covering the importance of engaging with and educating Small and Medium-Sized Enterprises (SME's) on the work of the regulator; the importance of understanding the international differences in regulatory requirements; improving trial design; ensuring the patient voice is properly heard via ILAP patient groups; how to ensure medical devices are adequately included; how to properly engage the early stage innovators and developers; and ensuring that fees are proportionate and competitive. It was noted that this last point will be considered by the Agency's Fees Strategy Group.

7.3 The Board commented that greater focus must be given to engaging with innovators at an earlier stage than has been done to date, noting that as more applicants progress through the process there will be more data to properly assess this. Other questions were raised on how to distinguish ILAP from the Early Access to Medicines Pathway and the Innovation Office, and how ILAP contributes to the work of the Accelerated Access Consortium.

7.4 There was clear feedback from the Board that there should not be a separate Critical Need Access Pathway for devices as most of the principles of ILAP could apply equally to devices and medicines. There will obviously need to be some adaptation of the pathway to accommodate the specific requirements of devices and the Board felt strongly that a consistent approach for the regulation of innovative medicines and devices would be a benefit. The use of the word 'Licensing' in the name of the pathway would have to be removed if devices are included and the Board encouraged the Agency to develop a more compelling brand name for the service than "ILAP".

7.5 The Board endorsed the overall direction of the development of an integrated regulatory and health technology assessment pathway to accelerate patient access to new medicine and medical device technologies. The Board also noted that the Agency would need to consult the other ILAP partners on the points raised in the meeting.

Action 46: The Board's comments on the future development and 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.

Sam Atkinson

PATIENT SAFETY

Item 8. What assurance can be provided by the Patient Safety & Engagement Committee?

8.1 The Board considered the assurance report from the Patient Safety and Engagement Committee (PSEC). At the third meeting, PSEC discussed an amendment to its Terms of Reference so that the assurance reports to the Board can be used as a more timely

public record of the meetings. The committee also discussed a report on the Cumberlege deliverables and asked for more data, detailed examples and evidence of impact. Finally, PSEC discussed its forward work programme.

8.2 The Board thanked Mercy Jeyasingham for the assurance report and welcomed the joint ARAC and PSEC Meeting that is being planned. However, the Chair emphasised that the two Board Committees must ensure their work does not overlap and create unnecessary duplication for the executives.

8.3 The Board noted the report.

EXTERNAL PERSPECTIVE

Item 9: 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. There were questions relating to quinolones; patients with neurodegenerative diseases; patient access to new medicines; the call for information to be considered as part of an expert review into isotretinoin; the Yellow Card Scheme; the blood cancer treatment Luspatercept; Covid-19 vaccination in pregnancy; and the Alzheimer's treatment Aducanumab.

Action 47: Review the status of the regulatory approval of Luspatercept and reply to the member of the public who submitted a question on this.

Sam Atkinson

Action 48: Include a summary of what we know about the impact of COVID-19 vaccines in pregnant women in the Weekly Summary of Yellow Card Reporting published on the MHRA website.

Rachel Bosworth

SUMMARY OF ACTIONS FROM MHRA BOARD MEETING IN PUBLIC – 15 June 2021

Action Number	Action	Owner	Date	Status
Carried Forward from previous meetings				
21	ARAC to review governance and risks of the new medical devices regulatory framework in conjunction with PSEC	Michael Whitehouse	~~18/05/21~~ 20/07/21	On agenda
22	Present an update to the Board on how the short, medium and long-term deliverables from IMMDSR are being measured over time.	June Raine	20/07/21	On agenda
27	ODRC to review Diversity and Inclusion to provide assurance to the Board	Anne-Toni Rodgers	~~20/04/21~~ ~~15/06/21~~ 20/07/21	On agenda
29	Present an Agency Laboratory Strategy to the Board as part of the Agency Science Strategy.	Chief Scientific & Innovation Officer	~~21/09/21~~ 16/11/21	
33	Consult members of the public on the branding of the Yellow Card Biobank.	Alison Cave	21/09/21	
34	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.	June Raine	~~18/05/21~~ 21/09/21	
36	Promote the NICE accreditation of the MHRA Drug Safety Update	Rachel Bosworth	~~15/06/21~~ 20/07/21	Verbal update
37	Start using the Balanced Scorecard to measure agency performance	Jon Fundrey	~~15/06/21~~ 20/07/21	On agenda
38	PSEC and ARAC to agree how to provide assurance to the Board on the development, governance and data standards of SafetyConnect	Mercy Jeyasingham and Michael Whitehouse	20/07/21	On agenda
39	Implement the approved Communications Strategy with particular focus on measuring trust and communications with HCPs	Rachel Bosworth	16/11/21	
New Actions				
41	Hold briefing for any Board Directors who wish to understand and reconcile the details of CPRD accounting.	Jon Fundrey	20/07/21	Verbal update
42	The Board approved the 2020/21 financial accounts in	Michael Whitehouse	20/07/21	Verbal update

	principle and delegated responsibility to the ARAC Chair to clear the final accounts for the Chief Executive to sign after the audit issues have been resolved. A written note should be provided to the Board to confirm this has been completed with assurance that the final accounts are not materially different from those considered by the Board.			
43	A revised assurance and governance framework for the new MHRA organisation should be presented to the Board.	Carly McGurry	15/02/22	
44	The Board approved the 2020/21 Annual Report in principle and delegated responsibility to the ARAC Chair to clear the final wording of the governance statement for the Chief Executive to sign after the audit issues have been resolved. A written note should be provided to the Board to confirm this has been completed with assurance that the final report is not materially different from the draft reviewed by the Board.	Michael Whitehouse	20/07/21	Verbal update
45	The Board were asked to provide any final typographical or wording comments on the Annual Report to Rachel Bosworth by 16 June.	All Board Directors	16/06/21	Verbal Update
46	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.	Sam Atkinson	19/10/21	
47	Review the status of the regulatory approval of Luspatercept and reply to the member of the public who submitted a question on this.	Sam Atkinson	20/07/21	Verbal update
48	Include a summary of what we know about the impact of COVID-19 vaccines in pregnant women in the Weekly Summary of Yellow Card Reporting published on the MHRA website.	Rachel Bosworth	20/07/21	Verbal update

Medicines & Healthcare products Regulatory Agency

Chief Executive's Report to the Board
20th July 2021

This report gives a brief overview of the current issues from the CEO's point of view. The Board is asked to consider and agree the priorities.

EXECUTIVE SUMMARY 'TOP 10' HEADLINES

- The Delivery Plan 2021-23 was published on 2 July, signalling a new era for MHRA, putting patients first, and was positively received by a wide range of stakeholders
- The Prime Minister visited NIBSC where he announced the UK's Science and Technology Council, a new initiative to cement UK's position as a science superpower
- Over 100 batches of COVID-19 vaccines have been certificated since December 2020, equating to more than 95m doses
- An Innovation Passport was awarded for LentiGlobin, a gene therapy for sickle cell disease – so far 34 applications for Innovation Passports have been received
- The G7 Therapeutics and Vaccines Clinical Trials Charter was launched to accelerate clinical trials and generate robust evidence for this and future pandemics
- Patient recruitment has begun into the virtual clinical effectiveness trial on oral anticoagulants in atrial fibrillation managed by CPRD and Birmingham University
- We extended the Exceptional Use Authorisation to Test and Trace for the Innova COVID-19 Lateral Flow Test to continue to supply the national testing programme
- Longstanding contraindications to the use of chloramphenicol eye drops in children under 2 years are being lifted on the basis of a review of the toxicity of the ingredients
- Patients have been invited to present to the Isotretinoin Expert Working Group regarding serious suspected sexual and psychiatric side effects of this acne treatment
- The Governance Office was launched, bringing together staff working on corporate governance, on risk, and on support for the Board and Executive committee.

HEALTHCARE ACCESS

COVID-19 vaccine independent testing by NIBSC

1. In June 2021, NIBSC has certificated a total of 17 batches of AZ, Pfizer and Moderna COVID-19 vaccines. This is the equivalent to approximately 16.4m doses. In total over 100 batches of COVID-19 vaccines have been certificated since December 2020 equating to more than 95m doses.

2. On Monday 21st June NIBSC was honoured to host a visit by the Prime Minister, who chose the visit to launch the UK's Science and Technology Council, a new initiative to cement the UK's position as a science superpower. These exciting plans were set to capitalise on the excellence of UK science throughout the pandemic and beyond, such as that carried out by the NIBSC in relation to COVID-19 vaccine quality control, COVID-19 testing and the essential reference materials to support safe availability of life-saving medicines around the world.

3. The Prime Minister saw first-hand the pivotal role NIBSC has played in assuring the quality of every COVID-19 vaccine used in the UK during the pandemic and heard about the vital work being carried out at NIBSC, including the essential laboratory work which supports NIBSC's global role in helping to determine the final flu vaccine composition each year. The thorough preparations from many staff resulted in an excellent visit, and a great example of cross Agency working. Following a briefing on the MHRA's comprehensive work as One Agency to ensure the safety of the public during the pandemic, the Prime Minister extended his thanks to all the Agency's staff.

COVID-19 vaccines clinical trials

4. The Clinical Trials Unit (CTU) continues to support vaccine developers, including clinical trials funded by DHSC. Early advice has been given for a potential trial of a third vaccine dose in immunocompromised subjects as well as for a trial evaluating use of COVID-19 vaccines in pregnant women. Early immunogenicity data for the COM-COV heterologous prime-boost vaccine trial was presented to the Vaccine Benefit Risk Expert Working Group, with initial data being positive.

Clinical Trials strategy

5. On 23 June the UK government and devolved administrations published the implementation plan setting out the first year of activities towards delivering the vision for The Future of UK Clinical Research Delivery. This represents the first phase of activity to ensure research will have better health outcomes and allow more patients to be involved in, and benefit from, research of relevance to them. Implementation and development of the next phase of delivery will be overseen by the DHSC's Recovery, Resilience and Growth (RRG) Programme. MHRA is leading on early advice services, support for innovative and decentralised trial designs, streamlining of approvals, data-enabled (CPRD) patient 'find and recruit' service, updating regulations, supporting expedited Phase 1 oncology trials, and supporting increased diversity in trials.

6. Publication of the plan follows on from the historic G7 Health Ministers' agreement to create a new Therapeutics and Vaccines Clinical Trials Charter setting out shared principles to accelerate the speed with which clinical trials generate robust evidence and how their findings can be implemented in this and future pandemics.

Innovative Licensing and Access Pathway

7. The Innovative Licensing and Access Pathway (ILAP) has now received 34 applications for the Innovation Passport designation from a variety of sponsors including large and small companies, and in common as well as rare diseases. Of the first 25 Innovation Passport applications, 8 have expressed interest in entering the US FDA's Project Orbis. The first Innovation Passport was awarded at the end of February to Belzutifan, a treatment for adults with von Hippel Lindau disease.

8. We have now received one request for a Target Development Profile (TDP) and we expect to deliver the roadmap document in the coming two months. We have set up a dedicated ILAP patient reference group with 16 representatives who will contribute to the decision making for the Innovation Passport designation and other patient activities such as developing the 'Enhanced patient engagement tool'. There are ongoing discussions with colleagues from Wales about formally joining the ILAP as a partner organisation.

Patient recruitment via CPRD into Atrial Fibrillation virtual clinical effectiveness trial

9. The University of Birmingham DaRe2THINK (D2T) trial aims to improve health outcomes of younger patients with atrial fibrillation by reducing the risk of stroke, blood clots, cognitive decline and vascular dementia. CPRD is facilitating patient recruitment from the CPRD GP practice network and managing the trial through CPRD's Interventional Research Services Platform. D2T is a virtual trial, the first of its kind in the UK, whereby patients consent remotely, medication is delivered to their homes, and monitoring and follow-up is through electronic health records (EHR) collected by CPRD. The trial commenced in June and the first six of the target 3000 patients have been recruited, with 61 GP practices already signed-up to take part.

10. The D2T trial employs a risk-adjusted and pragmatic approach to safety reporting, a process discussed with the Agency Innovation Office. Safety reporting will use both traditional reporting of adverse events by an Investigator, combined with monitoring a code-list for safety outcomes via CPRD EHR. This innovative multi-faceted approach will establish a precedent for use of EHR in safety monitoring in future randomised clinical trials.

First CPRD SPRINT patient recruitment service contract signed

11. CPRD has signed the first of several contracts currently undergoing negotiation, for the new CPRD SPRINT service supporting rapid patient recruitment into commercial sponsored clinical trials. The first CPRD SPRINT contract is with a Contract Research Organisation (CRO) to recruit 155 patients into a phase 3 cardiovascular trial with CPRD facilitated recruitment commencing in August 2021. Both pharmaceutical companies and CROs continue to show a high level of interest in CPRD SPRINT and there are many other studies in addition to those in contract negotiations that are under active discussion.

NIBSC Annual WHO Standards planning meeting

12. NIBSC held its annual WHO standards meeting attended by around 70 staff, with 6 attendees from WHO where the projects being prepared for submission to the Expert Committee for Biological Standardisation (ECBS) in 2021, were reviewed and discussed. NIBSC will submit 8 projects for adoption at this year's ECBS meeting: new WHO standards for Lassa fever virus antibody, Mycobacterium tuberculosis DNA, Varicella Zoster Virus DNA and anti-thyroid peroxidase antibodies, plus replacement WHO standards for diphtheria antitoxin equine, Ferritin (human recombinant), von-Willebrand factor concentrate and Follicle Stimulating Hormone. These standards will support the development and calibration of diagnostic assays, calibration of assays used to determine potency and ensure accurate dosing of therapeutic products, and calibration of assays used to determine patient response to vaccination.

Agency Horizon Scanning input to NIHR-led workshop on the UK COVID-19 story

13. The Agency Horizon Scanning Strategic Lead was a member of a panel at a National Institute for Health Research Health Technology Assessment (NIHR HTAi) 2021 workshop on Sunday 20th June (https://htai.eventsair.com/htai-manchester-2021-am/workshops) entitled "Providing intelligence to support an accelerated innovation pathway: A UK COVID-19 Story". Talks were given by colleagues from NIHR and NICE and discussions were held afterwards relating to how horizon scanning has supported a multi-agency initiative, the RAPID-C19 (Research to Access Pathway for Investigational Drugs for COVID-19). MHRA have been involved in weekly/fortnightly horizon scanning meetings to support RAPID-C19 since the beginning of the pandemic in Spring 2020.

PARTNERSHIPS NATIONAL AND INTERNATIONAL

International regulatory collaboration

14. The Access Consortium (a coalition of the regulatory authorities for Australia, Canada, Switzerland, Singapore and UK) heads of agencies have developed the Access Strategic Plan for 2021-2024 and this has been published on the gov.uk website. This plan will guide Access member countries towards enhanced efficiency of our national regulatory systems, while optimising synergies and alignment between regulatory authorities and reducing duplication for industry. The MHRA has also received its first marketing authorisation application under the new active substance work-sharing initiative.

FDA Project Orbis

15. The MHRA is now a full participant in Project Orbis, a programme involving the regulatory authorities of Australia, Canada, United Kingdom, Singapore, Switzerland and Brazil and coordinated by the US Food and Drug Administration (FDA), to review and give expedited approval to promising cancer treatments. MHRA has completed assessment of several novel products and sought advice from CHM. The products include Trovelvy (a Trop-2-directed antibody and topoisomerase inhibitor conjugate for triple negative breast cancer), Belumosudil (in the treatment of graft versus host disease), Lumykras for the treatment of adult patients with KRAS G12C mutated metastatic non-small cell lung cancer and a variation for Lorviqua (for the treatment of adult patients with ALK-positive advanced lung cancer where disease has progressed after other treatments). These will be processed to completion in the next few weeks.

Bilateral Conference with the Chinese National Medical Products Administration

16. On 9 June 2021 a bilateral conference was held to officially launch the program of workshops which MHRA is delivering to the Chinese National Medical Products Administration (NMPA). This was attended by Her Majesty's Trade Commissioner John Edwards, NMPA Deputy Commissioner Chen Shifei, and MHRA CEO along with officials from each organisation. The Conference reviewed the workshops on clinical trials delivered earlier in the year and celebrated the strengthening of the regulatory relationship between the MHRA and NMPA.

Collaboration with the Health Research Authority

17. The combined regulatory and ethics review service for clinical trials took another step forward in June. The IT system supporting the service was upgraded to facilitate submission of annual safety reports via the Integrated Research Application System (IRAS). This work is a further step towards delivering a single UK 'front door' for clinical trials. A final system upgrade in September will allow clinical trial sponsors using combined review to manage the complete lifecycle of their trial via the IRAS system. The scale-up of combined review is tracking to target to achieve the goal of all applications entering this system by the start of 2022. This has been supported by a communications drive at the end of May which has seen a significant increase in registrations to the new system.

PATIENT SAFETY

COVID-19 vaccines safety

18. We continue to publish weekly reports of all suspected Adverse Drug Reactions (ADRs) in association with COVID-19 vaccines received via the Yellow Card Scheme up to 23 June 2021, for the UK. For the Pfizer/BioNTech vaccine, COVID-19 Vaccine AstraZeneca and COVID-19 Vaccine Moderna the overall reporting rate is around 3 to 7 Yellow Cards per 1,000 doses administered.

19. The MHRA has undertaken a thorough review into UK reports of an extremely rare specific type of blood clot in the brain, known as cerebral venous sinus thrombosis (CVST) occurring together with low levels of platelets (thrombocytopenia) following vaccination with the COVID-19 Vaccine AstraZeneca. We are also considering other blood clotting cases (thromboembolic events) alongside low platelet levels. This ongoing scientific review has concluded that the evidence of a link with COVID-19 Vaccine AstraZeneca is stronger and an announcement was made on 7 April 2021 with a further statement on 7 May. We have continued to publish the latest breakdown of all cases of these extremely rare side effects on a weekly basis and updated information on cases received up to 23 June 2021. Our advice remains unchanged that the balance of benefits and risks of all of the COVID-19 vaccines deployed in UK remains favourable.

COVID-19 Tests

20. The MHRA requested information from DHSC/NHS Test and Trace to ascertain if the concerns of the US Food and Drug Administration (FDA) regarding Lateral Flow tests manufactured by Innova Medical Group had any implications for UK. Following a rapid review of the data provided we were satisfied that DHSC/NHS Test and Trace have the necessary Quality Management Systems in place to successfully reduce risks. Following this satisfactory outcome MHRA extended the Exceptional Use Authorisation EUA to DHSC/NHS Test and Trace to continue to supply the national testing programme to find positive cases in asymptomatic individuals.

Safety of acne treatment isotretinoin

21. We are now reaching the next milestone for the Commission on Human Medicines (CHM) review of psychiatric and sexual side effects suspected to be associated with isotretinoin. The CHM's Isotretinoin Expert Working Group (IEWG) is carefully considering all of the available information. To aid the assessment of these important concerns, the IEWG has invited patients and other stakeholders to attend meetings to present their views on how the possible risks associated with isotretinoin could be best managed. The IEWG will hear any additional information directly from patients and stakeholders that has not already been provided through the public consultation or via the Yellow Card scheme. Patients and stakeholders were contacted to register their interest in attending & information was published on the GOV.UK review page and on social media. All who registered an interest have been offered the opportunity to present. We are holding preparatory meetings to familiarise patients and other stakeholders with how the IEWG meetings will be run.

Chloramphenicol eye drops

22. The Paediatric Medicines Expert Advisory Group (PMEAG) of the CHM advised on changes to Chloramphenicol eye drops products in the UK and their use in children below the age of 2 years. Recent implementation of the EMA excipient guideline and related labelling updates for boric acid containing products regarding potential effects on fertility led to restriction of paediatric use in children under 2 years which had the potential for serious clinical implications. We reviewed the evidence available to understand the risk for paediatric patients when using these products for short course of treatment within the licenced indication of eye infection. Based on exposure calculations for current clinical use and the acceptable safety margins in place for the indicated uses in 0-2 year olds, the PMEAG agreed that the warnings and contraindications currently implemented in all chloramphenicol containing products should be reversed to allow use in children of all ages.

National Patient Safety Alerts and Medicines Recalls

23. During June, four National Patient Safety Alerts were issued. Two were high impact recalls to patient and pharmacy level respectively and were issued following rapid and informed decision making in the interests of patient safety. A batch of Co-codamol 30/500 Effervescent Tablets was recalled due to varying levels of active ingredients present in the tablets, and batches of a number of medicines were recalled as batches had been identified to be contaminated with an impurity of mutagenic potential (azido-tetrazole).

Medical devices sterilised by Steril Milano – potential for incomplete sterilisation

24. We have recently issued the following devices safety information messages to the health care system in connection with Steril Milano, a third party provider of sterilisation services to some medical devices manufacturers. Fraudulent activity by this third-party sterilisation provider has been identified and multiple medical device manufacturers have been affected. We proactively asked manufacturers to undertake a risk assessment and notify MHRA of planned actions to mitigate risks of further incidents, conducted thorough risk assessments and have worked with cross-system groups to minimise disruption to healthcare and ensure appropriate actions. We published additional safety information relating to specific manufacturers to mitigate the risks. We are collaborating with international medical device regulators, sharing best practice and information on field safety corrective actions and recalls.

Devices manufactured by Phillips

25. We issued a National Patient Safety Alert in connection with Continuous Positive Airways Pressure and Bilevel Positive Airway Pressure devices manufactured by Phillips due to two identified safety issues related to degradation of the sound abatement foam found in these devices.

Future Linkage of MHRA Device Registrations

26. In the future, NHS Digital will use MHRA's device registration information as reference data for their Medical Device Information System (MDIS). In order to assist in the development of the MDIS programme we have reviewed information about class III and IIb devices registered on the MHRA system from 1 January 2021 by the "top 10" manufacturers of devices (and their subsidiaries) supplying to the NHS (as identified by NHSX/NHS Digital). These "top 10" manufacturers have already registered over 130,000 implantable devices on the MHRA registration system.

27. Our analysis revealed that while 97% of the registration submissions contained catalogue/reference numbers, only 18.5% contained Unique Device Identifier (UDI-DI) information, which is required to identify devices unambiguously. Although not frequently submitted, the UDI-DI data provided was submitted in the correct format. This illustrates why the planned future GB medical device legislation will need to mandate both the submission of this UDI-DI data and the ability to share the registry data with NHS Digital, healthcare professionals and patients in a transparent and useful manner.

Enforcement activities

28. Operation Pangea was undertaken between 18th – 25th May and, in partnership with Border Force, approximately 1500 packages were inspected at postal hubs. A total of 930,000 doses of medicines worth £2.8 million were seized. Additionally, around 110,000 URLs illegally offering medicines / medical devices were identified and to date approximately 33,000 have been removed. A further 1.2 million doses of unlicensed medicines were seized as a result of collaborative working with UK Border Force and MHRA participation in Operation Pangea. Three account freezing orders were granted

by the courts and a further 32 court orders were obtained in support of criminal investigations.

DYNAMIC ORGANISATION

Delivery Plan 2021-23

29. The MHRA Delivery Plan 2021-23 has been positively received and we have engaged a wide group of stakeholders as well as our Patient Group Consultative Forum. An abridged version was sent to both groups to set out our ambition, together with a link to the comprehensive Delivery Plan for full detail. The Delivery Plan has also been sent to the co-chairs of both the "First Do No Harm" All-Party Parliamentary Group (Lady Cumberlege and Rt Hon Jeremy Hunt MP) and the Independent Medicines and Medical Device Safety Review Patient Reference Group. Tailored presentations are being used in bilateral meetings with key partners who are critical to successful delivery of the Delivery Plan.

Governance Office

30. As an early 'pathfinder' within the Agency's Transformation Programme, the new Governance Office 'launched' this month, bringing together staff working on risk, corporate governance and support for the Board and Executive committees for the first time. Further work is needed through the Agency wide consultation to confirm exactly how we transfer services for expert and advisory committees to the Governance Office, as well as to confirm the final scope and design of the Office. The team involved have been very positive about the new opportunities that the creation of the Governance Office brings to each of their areas of responsibility. Further communication will be shared with the rest of the Agency as part of the ongoing Transformation Programme strategy.

FINANCIAL SUSTAINABILITY

Upcoming Spending Review

31. Work is under way to define our bid for the forthcoming comprehensive Spending Review. The initial target is to set out our initial thoughts and seek feedback from our sponsor team at the next Quarterly Accountability meeting on the 5 August 2021.

Finance Transformation

32. Work continues on Phase II of Finance Transformation which has two key workstreams – firstly, the automation of back office processes and currently manual data interfaces to Oracle Fusion, our ERP system, which will enable the Finance team to operate with the reduced headcount following the redesign of the Finance function in Phase I. The second workstream is to acquire and implement a planning and budgeting system which will improve the way we budget, ensuring we have 'one version of the truth'. We also intend to develop two further 'modules' to cover Profitability and Workforce planning with the former delivering a monthly status on our fees and costs without having to undertake significant one-off analyses. This will ensure we are best placed to closely monitor the impact of any new fees structure.

June Raine
Chief Executive
July 2021

Medicines & Healthcare products Regulatory Agency

BOARD MEETING HELD IN PUBLIC

20 July 2021

Title	What is the current performance of the MHRA on the Balanced Scorecard?
Board Sponsor	Jon Fundrey
Purpose of Paper	Assurance

What is the current performance of the MHRA on the Balanced Scorecard?

1. Executive Summary

1.1 This paper sets out commentary to support the Monthly Balanced scorecard detailed in the attached appendices.

1.2 The Board is being asked to review the metrics and the commentary and consider whether this provides appropriate assurance that current performance is on track and aligned to our strategic objectives.

2. Introduction

2.1 The monthly balanced scorecard has been updated with data up to 31 May 2021. It is important to note that, as this is the monthly version of the scorecard, it does not include the full suite of metrics included in the quarterly version. A list of metrics included in the monthly and quarterly versions, with the current status of those metrics, is included in section 3.7.

2.2 Discussions around targets are ongoing with the divisions. We are anticipating significant progress on ensuring all metrics have a target by the September update.

3. Commentary

Scientific Innovation

3.1 With regard to clinical trials, the following is noted

- Following exit from the EU the UK remains a favourable place to conduct clinical research as numbers have remained at similar levels throughout.
- A key aspect is the increased use of novel trial designs for some pivotal COVID-19 trials (such as Recovery), which supported the MHRA position that such trial designs are acceptable to the regulator, can provide actionable results and do not necessarily have to be complex to conduct. The continued submission of such trial designs is encouraging, and an area that MHRA Clinical Trials Unit will continue to support (for example through ILAP).

Healthcare Access

3.2 The Innovative Licensing and Access Pathway **(ILAP)** is a new offer that supports innovative approaches to the safe, timely and efficient development of medicines to improve patient access.

- Demand from the market for this service has been much higher than anticipated. 28 applications were received in the first 5 months of 2021, double the anticipated amount.
- As this product is not currently cost recovering, we will need to request additional funding in our Spending Review bid to cover the increased activity.

3.3 The early access to medicines scheme **(EAMS)** aims to give patients with life threatening or seriously debilitating conditions access to medicines that do not yet have a marketing authorisation.

- The first step, the promising innovative medicine (PIM) designation, gives an indication that a product may be eligible for EAMS based on early clinical data. The numbers of PIM application have remained steady during the reporting period and in line with predicted activity
- The second step, the scientific opinion, describes the risks and benefits of the medicine. The activity for the scientific opinion is less than expected and may reflect the new status of the UK being outside of the EU. A new proposed legal provision designed to enhance EAMS may create additional activity.

3.4 A Fusion error means the device registrations metric has not been updated and this is currently being working on.

Patient Safety

3.5 With regard to adverse drug reactions, the following is noted

- Huge spike in adverse drug reactions, increase of over 1,200% from Q3 to Q4 with similar levels being shown in Q1 so far. This is due to the release of the Coronavirus Yellow Card reporting site and was an expected increase.
- This has contributed to the number of patient safety interventions almost doubling.

Dynamic Organisation and Financial Sustainability

3.6 With regard to finances and headcount, the following is noted

- As a result of the current recruitment freeze Full Time Equivalent (FTE) numbers have fallen by 1% to 1,372 since the start of the financial year. We had budgeted on recruiting up to an FTE of 1,458.
- This variance has contributed to staff costs being £1.6m under budget YTD. IT costs to date are also £2.1m below budget but we expect the majority of this is a timing variance only.
- The reduced costs have contributed towards a £3.2m YTD operating surplus, but we are still expecting a deficit of around £1m by the end of the financial year. Size and Shape progress and impact could significantly change this projection, a reforecast will be completed once more information is known.
- Cash balance increased by £7m from April to May due to receiving £10m of service fee payments. We expect the cash balance to fall significantly in the second half of the year once we are incurring higher project costs and have already collected most of the service fee income.
- Any cash reserves remaining at the end of this financial year will be transferred to the Treasury due to the loss of the Agency's Trading Fund status.

3.7 The metrics status is as follows:

Item No.	**Goals**	**BS Metric**	**Quarterly**	**Monthly**	**Live Data/Sample**
1	HEALTHCARE ACCESS	Variation determinations	Yes	Yes	Live
2	HEALTHCARE ACCESS	Generic approvals	Yes	Yes	Live
3	HEALTHCARE ACCESS	NAS determinations	Yes	Yes	Live
4	HEALTHCARE ACCESS	Standards sales volumes	Yes	Yes	Live
5	HEALTHCARE ACCESS	ILAP applications	Yes	Yes	Live
6	HEALTHCARE ACCESS	EAM PIM applications	Yes	Yes	Live
7	HEALTHCARE ACCESS	Device registrations	Yes	Yes	Not updated
8	HEALTHCARE ACCESS	PIPS volumes	Yes	Yes	Live
9	PATIENT SAFETY	Adverse drug reactions	Yes	Yes	Live
10	PATIENT SAFETY	Adverse device incidents	Yes	Yes	Live
11	PATIENT SAFETY	Adverse blood reactions	Yes	Yes	Live
12	PATIENT SAFETY	Patient safety interventions	Yes	Yes	Live
13	SCIENTIFIC INNOVATION	Clinical Trials	Yes	Yes	Live
14	SCIENTIFIC INNOVATION	Grants % success rate	Yes	No	Sample
15	SCIENTIFIC INNOVATION	Research papers - Impact Score	Yes	No	Sample
16	SCIENTIFIC INNOVATION	CPRD UK population coverage	Yes	No	Sample
17	SCIENTIFIC INNOVATION	Publications using CPRD data	Yes	No	Sample
18	FINANCIAL SUSTAINABILITY	Projected year end surplus	Yes	Yes	Live
19	FINANCIAL SUSTAINABILITY	Cash balance	Yes	Yes	Live
20	FINANCIAL SUSTAINABILITY	Corporate overhead %	Yes	No	Live
21	FINANCIAL SUSTAINABILITY	Non-pay savings	Yes	No	Sample
22	FINANCIAL SUSTAINABILITY	Cashable Benefits	Yes	No	Live
23	DYNAMIC ORGANISATION	FTE	Yes	Yes	Live
24	DYNAMIC ORGANISATION	People engagement score	Yes	No	Sample
25	DYNAMIC ORGANISATION	Key project milestones missed	Yes	No	Live
26	DYNAMIC ORGANISATION	Indexed productivity	Yes	No	Sample
27	PATIENT & PUBLIC INVOLVEMENT	Public communications engagement	Yes	No	Sample
28	PATIENT & PUBLIC INVOLVEMENT	Reputational index	Yes	No	Sample
29	PATIENT & PUBLIC INVOLVEMENT	Positive media sentiment	Yes	No	Sample

4. Recommendation

4.1 The Board is asked to confirm that the Monthly Balanced Scorecard presented provides assurance that current performance is on track and aligned to strategic objectives

Jon Fundrey
20 July 2021

Medicines & Healthcare products Regulatory Agency

Balanced Scorecard (Monthly View) v1.0

May 2021 – 1/4

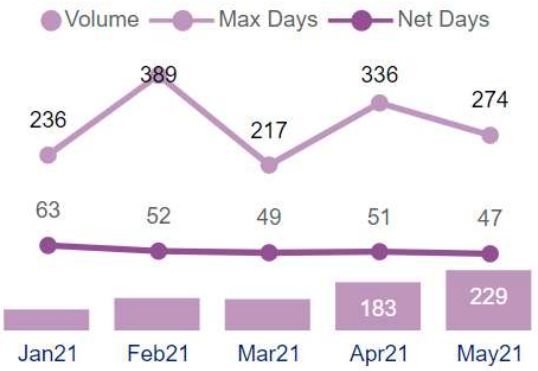
Healthcare access

Variations - Net Days to Determination

47
Target: 120

KPI

Trend



Generics - Net Days to Approval (inc Total Volume on Chart)

National MAs

212
Target: 210

KPI

Trend

EC Reliance

47
Target: 67

KPI

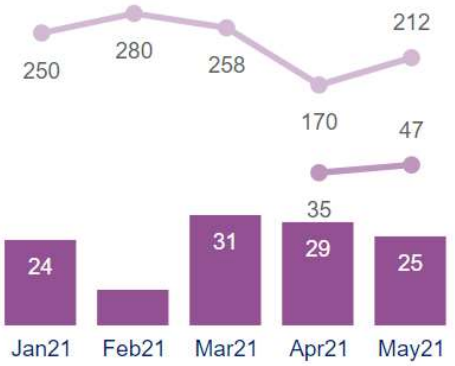
Trend

MRDC Reliance

(Blank)
Target: 67

KPI

Trend



NAS - Net Days to Determination (inc Total Volume on Chart)

EC Reliance

47
Target: 67

KPI

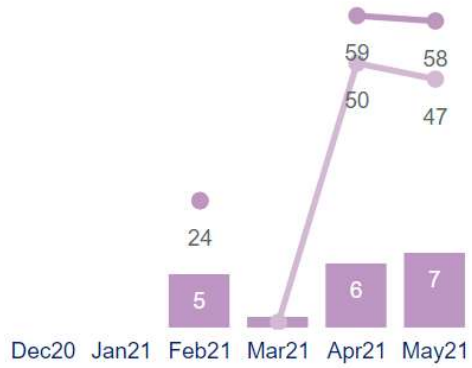
Trend

PL(GB)/Orbit/Access

58
Target: 210

KPI

Trend

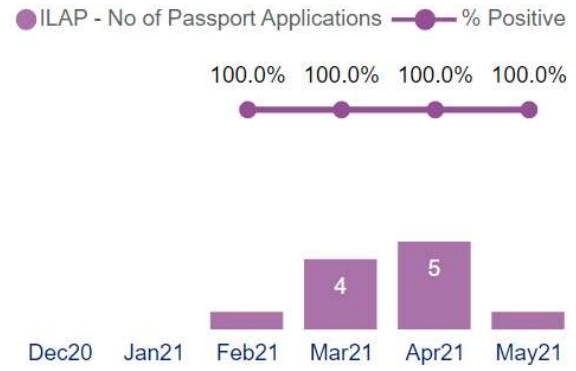


ILAP Passport Applications

100%

KPI

Trend



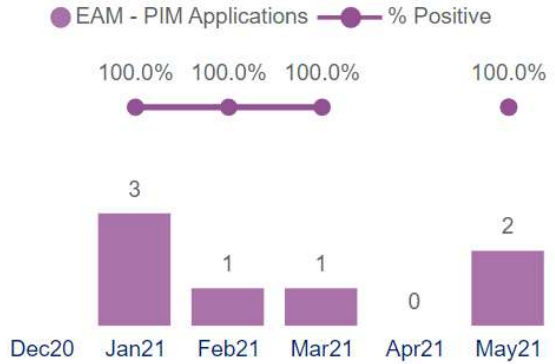
Healthcare access

EAM PIM Applications

100%

KPI

Trend



Device Registrations

Deadline 01/05/21

536,459

Deadline 01/09/21

117,051

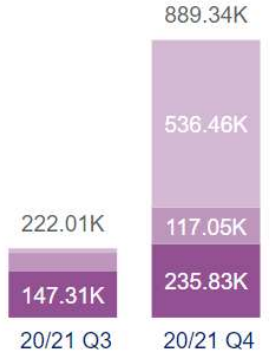
Deadline 01/01/22

235,833

KPI Trend

KPI Trend

KPI Trend



Standards Sales Volume

NIBSC (Non Flu)

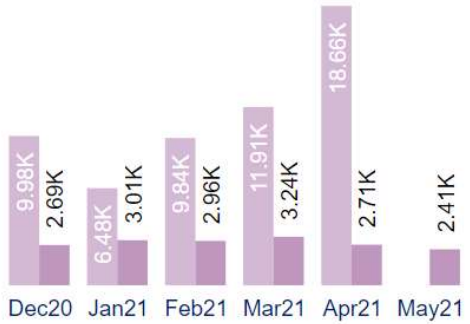
18,659

BP

2,405

KPI Trend

KPI Trend



PIPS Volume

15

KPI

Trend

Medicines & Healthcare products Regulatory Agency

Balanced Scorecard (Monthly View) v1.0

Patient safety

Adverse Drug Reactions

51,576

KPI

Trend

Devices - Adverse Incidents

2,512

KPI

Trend

Adverse Blood Reactions

63

KPI

Trend

Patient Safety Interventions

Major Signals

24,098

Manuf Safety Comms

2

MHRA Safety Comms

3

KPI

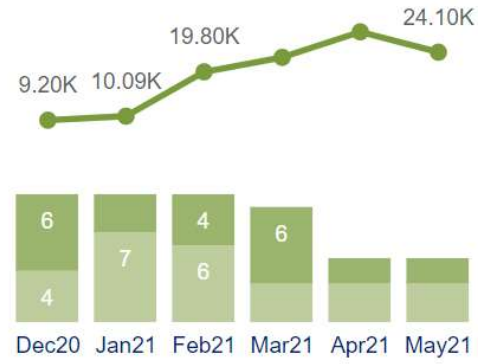
Trend

KPI

Trend

KPI

Trend



Medicines & Healthcare products Regulatory Agency

Balanced Scorecard (Monthly View) v1.0

May 2021 – 4/4

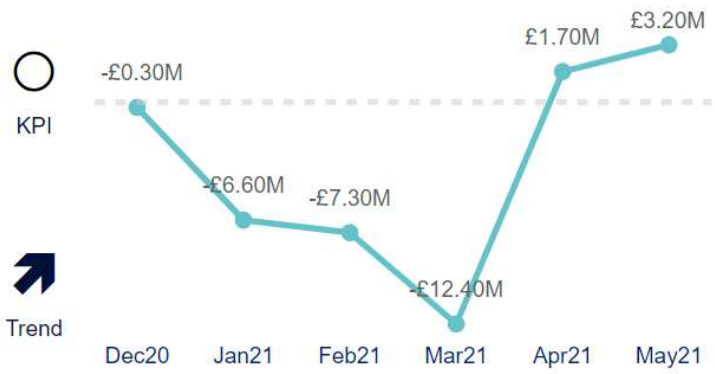
Financial sustainability

Year To Date Operational Surplus/Deficit

£3.20M

KPI

Trend

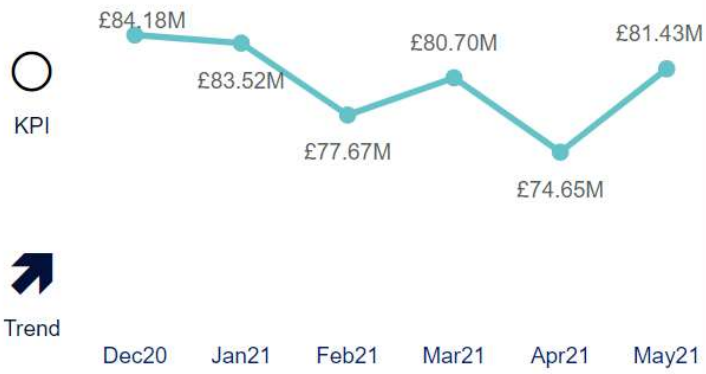


Cash Balance - Available Reserve

£81.43M

KPI

Trend



Dynamic organisation

FTE

1,372

KPI

Trend

Scientific innovation

Clinical Trials

Normal

58

Novel

1

FIH Approvals

7

KPI

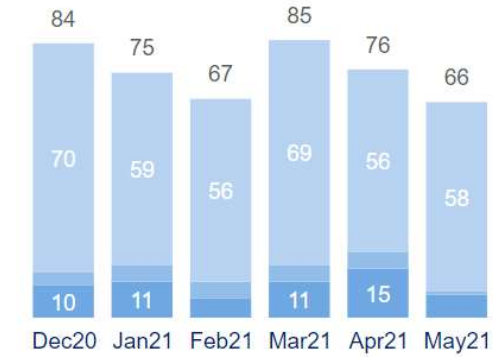
Trend

KPI

Trend

KPI

Trend



Medicines & Healthcare products Regulatory Agency

BOARD MEETING HELD IN PUBLIC

20 July 2021

Title	What progress is being made on the short, medium and long-term deliverables from the Cumberlege Review and how is their impact being measured?
Board Sponsor	June Raine and Mercy Jeyasingham
Purpose of Paper	Assurance

What progress is being made on the short, medium, and long-term deliverables from the Cumberlege Review and how is their impact being measured?

1. Executive Summary

1.1 One year on from the publication of the Cumberlege Review (the Independent Medicines and Medical Devices Safety Review, IMMDSR) on 8th July 2020, this is an important timepoint to assess the Agency's progress in delivering the range of changes needed to put patients at the centre of everything we do . The Agency's key goals and objectives to deliver these changes are laid out in the Agency Delivery Plan 2021-23: "Putting patients first: A new era for our agency", which was published on 2nd July 2021.

1.2 The Board has previously endorsed the Agency's planned short, medium, and long-term deliverables in response to the Cumberlege Review, and progress has been kept under review at the Patient Safety and Engagement Committee. This paper outlines what has been achieved so far, and how we propose to measure the impact of the actions we are implementing as a direct result of the Cumberlege Report's findings and recommendations.

1.3 The measures to monitor impact need further development and refinement and we propose, among other actions, to seek the views of the Patient Reference Group established by the DHSC which includes representation of all the groups whose concerns are addressed in the Cumberlege Review. The Board is asked to provide comments and endorsement of proposed next steps.

2. Introduction

2.1 The Cumberlege Report sets out the evidence obtained during two years of hearings and other information gathering regarding how women who received sodium valproate, pelvic mesh implants and hormone pregnancy tests were failed by the healthcare system. The systems which should have identified risks were slow and public awareness of these systems was low, and the responses in terms of listening to and acting on women's concerns were inadequate.

2.2 Recommendation 6 of the IMMDS Review states: *The MHRA needs substantial revision, particularly in relation to adverse event reporting and medical device regulation. It needs to ensure that it engages more with patients and their outcomes. It needs to raise awareness of its public protection roles and to ensure that patients have an integral role in its work.* There are also several 'Actions for Improvement' identified in the Review report for the Agency to implement.

3. Action taken so far

3.1 The Government Response includes a detailed contribution on the work which the Agency is undertaking and the progress made so far in the following range of

areas: to strengthen the regulatory framework for medicines and devices, improve adverse event reporting, improve patient involvement, improve the safety of medicines in pregnancy and transform our culture.

3.2 The Agency has made addressing the Review's concerns central to its new corporate Delivery Plan for 2021-2023 'Putting patients first - A new era for our Agency'. Involving patients in all our activities is the Agency's first priority and every member of staff will have an objective to help deliver better patient involvement. The Delivery Plan details the specific actions designed to address the Review's concerns.

Strengthened Agency Governance regarding patient safety

3.3 Two important steps have been taken to strengthen the Agency's governance in relation to patient safety. First, the MHRA Chief Safety Officer has been appointed and will be in post from 19th July, accountable for safety and surveillance for all health care products, including medicines and medical devices. A member of the Agency Board, the Chief Safety Officer is responsible for ensuring that the Agency's response to the Cumberlege Review is delivered.

3.4 Secondly, the new Patient Safety and Engagement Committee (PSEC) has been established, which advises and provides assurance to the Board in relation to the Agency's responsibilities regarding patient safety and involvement. The PSEC has considered the proposals to strengthen the Yellow Card Scheme and the Patient and Public Involvement Strategy in detail and provided critical input on both.

Patient and Public Engagement and Involvement

3.5 The first draft of the MHRA's Patient and Public Involvement (PPI) Strategy was informed and developed in 2020 and finished final public consultation at the end of June 2021 following its consideration by the Patient Safety and Engagement Committee and the Board earlier this year. The outcome of the public consultation will inform the strategy to be published before the end of the summer.

3.6 The strategy sets out five areas of focus to address:

- How we improve our involvement of patients
- How we improve our responsiveness to patient concerns
- How we will work with healthcare partners in ensuring a system-wide response to patient concerns
- How we will measure our progress in ways meaningful to patients
- How we transform our culture to deliver the change required

3.7 A meeting with the IMMDSR Patient Reference Group (PRG) was held in April 2021 to engage the Group in MHRA planning and a further meeting will be held on 29th July when we will use the opportunity to look at the emerging results of the PPI strategy consultation, find out what patients consider as the key elements and help finalise the strategy to obtain the maximum value. We will also involve the PRG in developing the meaningful measures of impact.

3.8 We are building on previous work with the established MHRA Patient Group Consultative Forum (PGCF). There has been a significant increase in the range of activities in which Agency staff seek to engage with patients from the Patient Group Consultative Forum, which is an excellent positive indicator. However, we recognise that it is vital that we ensure that this engagement is meaningful. Some examples of this include:

- The new Innovative Licensing & Access Pathway (ILAP) is building patient involvement at critical points. A pilot ILAP Patient Reference Group has already been created, agreeing Terms of Reference and patient involvement in the Steering Committee as well as inputting into the development of the Patient Engagement Tool. The role of ILAP partnerships is central to this requiring agreement with NICE and the Scottish Medicines Consortium. Measures of impact will include the patent perspective on clinical trial design and the inclusion of Patient Reported Outcome Measures.

- Patient workshops We have conducted a number of workshops with patients from the PGCF to inform our approach to different strategic issues. An example of this was the workshop to discuss how best to involve patients in shaping future rules for medical devices and how best to ensure the patient voice is integrated. This work has informed the approach for the forthcoming public consultation on the future medical device regulations.

- COVID-19 communications The Patient Group Consultative Forum has also played a key role in helping inform and shape our COVID-19 communications where we have tested vaccination leaflets and letters with patient representatives before publication. We recognise the importance of reaching out to patients on the vaccination programme and we have provided speakers to address issues on vaccine hesitancy with excluded groups to help improve take-up.

3.9 Patient involvement in regulatory decisions will provide an important basis for evaluating measures of impact of the change in the MHRA's approach to involving patients. The recent novel reclassification of the 'mini-Pill' (desogestrel) for Pharmacy availability included a formal patient engagement exercise as well as healthcare professional engagement on the initial proposal. The views of patients ensured that the decision to move to over-the-counter supply was accompanied by a suite of information enabling safe and effective use without the need for medical oversight. The patient voice also helped in the development of the supply 'model' including agreeing the level of professional support in the pharmacy setting.

3.10 Plans are now in place to hear directly from patients and their families at the Isotretinoin Expert Working Group of the Commission on Human Medicines at two meetings in July. This is the first time the MHA will have undertaken this direct listening to patients and follows an extensive public call for evidence during which around 500 responses were received from patients and their families.

Responsive safety reporting system

3.11 The building of the new responsive safety system which will ensure prompt identification of safety signals for both medicines and medical devices is now well under way. The 'SafetyConnect' programme of work is up and running to introduce a new vigilance service and new IT systems to detect and respond to safety concerns with any medicine, medical device or blood product more quickly and more comprehensively than ever before, with governance processes in place to ensure that the work is advanced according to milestones and that benefits are realised.

3.12 Patients and the public have been involved in the design stage of SafetyConnect and this has directly impacted on how the Agency monitors and acts on safety insights across the full product lifecycle, through joined up safety vigilance, reporting and information. We are continuing to engage with the public directly in gaining user feedback and perceptions on the SafetyConnect programme of work through user needs sessions and the feedback gathered through these sessions is being used to help ensure requirements of the new system are met.

3.13 The SafetyConnect system will be fully operational from March 2022 and measures of impact will range from patient reporting of adverse incidents, patient involvement in signal evaluation and the patient contribution to regulatory decisions, including the kind of information patients need to support individual decisions on risk.

Strengthened evidence for decision making

3.14 As well as highlighting the need for a safety system which responds promptly to patient reports of harm associated with medicines and medical devices, the Cumberlege Review emphasised the need for better evidence especially on long term safety. Over the last year there has been progress on two fronts: the mesh registry, which is overseen by DHSC, and the Valproate Registry.

3.15 The Valproate Registry was established in collaboration with NHS Digital and has helped us to understand the use of valproate in women of childbearing potential and the impact of valproate use on maternal and child health, and to facilitate further research on the safety of valproate, in particular with regard to child outcomes. The first report of the registry was published in February 2021 and the second report, which is planned for September 2021 will include data on all anti-epileptics, which was recommended in the Report of the IMMDS Review.

3.16 The next steps for the valproate registry are the building and integration of a digitalised 'annual risk acknowledgement form' into the registry to enable us to fully monitor adherence to the Pregnancy Prevention Programme. There are also plans to extend the registry to the whole of the UK, and to enable women themselves to add data to the registry to inform its findings.

3.17 We are also working closely with the NHSE/I Valproate Safety Implementation Group which has set up three work streams: stopping initiation and deprescribing valproate where safer alternatives are available and making dispensing safer; ensuring patients in this group who do take valproate have access to highly effective contraception, sexual and reproductive health advice and ensuring shared decision making is in place whenever valproate is prescribed to people who can get pregnant.

Strengthening medicines and medical devices regulation

3.18 In order to fully implement the changes required by the Cumberlege Review it was clear that change in the legislative framework for medicines and medical devices would be needed. Public consultations to be launched over the Summer on our legislative proposals under the Medicines and Medical Devices Act are in advanced preparation.

3.19 For the future devices regulatory regime, we have held a number of informal engagement sessions with all stakeholder groups to develop the policy proposals to be consulted on. The proposals aim to enhance patient safety, protect supply of devices to the GB market and provide access to devices, and to draw on international best practice.

3.20 For medicines, we are working closely with DHSC colleagues on provisions to enable pharmacists to supply medicines in the whole original pack, rather than in the exact quantity prescribed by the doctor. This will ensure that all necessary safety information will always be provided to the patient and includes placing a requirement on pharmacy professionals to always dispense sodium valproate in its original pack.

3.21 We are also seeking additional primary powers, using the forthcoming Health and Care Bill to facilitate medicines registries, to further support our safety monitoring activities. We have been working closely with NHS X and NHS Digital to prepare draft clauses which will enable NHS Digital to collect detailed information about the use of specific medicines and their effects in an information system(s) following recommendations from the Commission on Human Medicines (CHM), and share that data with MHRA to establish and maintain comprehensive UK-wide medicines registries.

3.22 The aim is to ensure that all patients prescribed a specific medicine are known to the registry, so that we can provide patients and their prescribers with the evidence they need to make more fully informed decisions and ensure that prescribing is in line with guidance on a medicine’s safe use and regulatory actions are having the desired impact. The impact of each registry initiated under these powers will be assessed as part of their individual work plans.

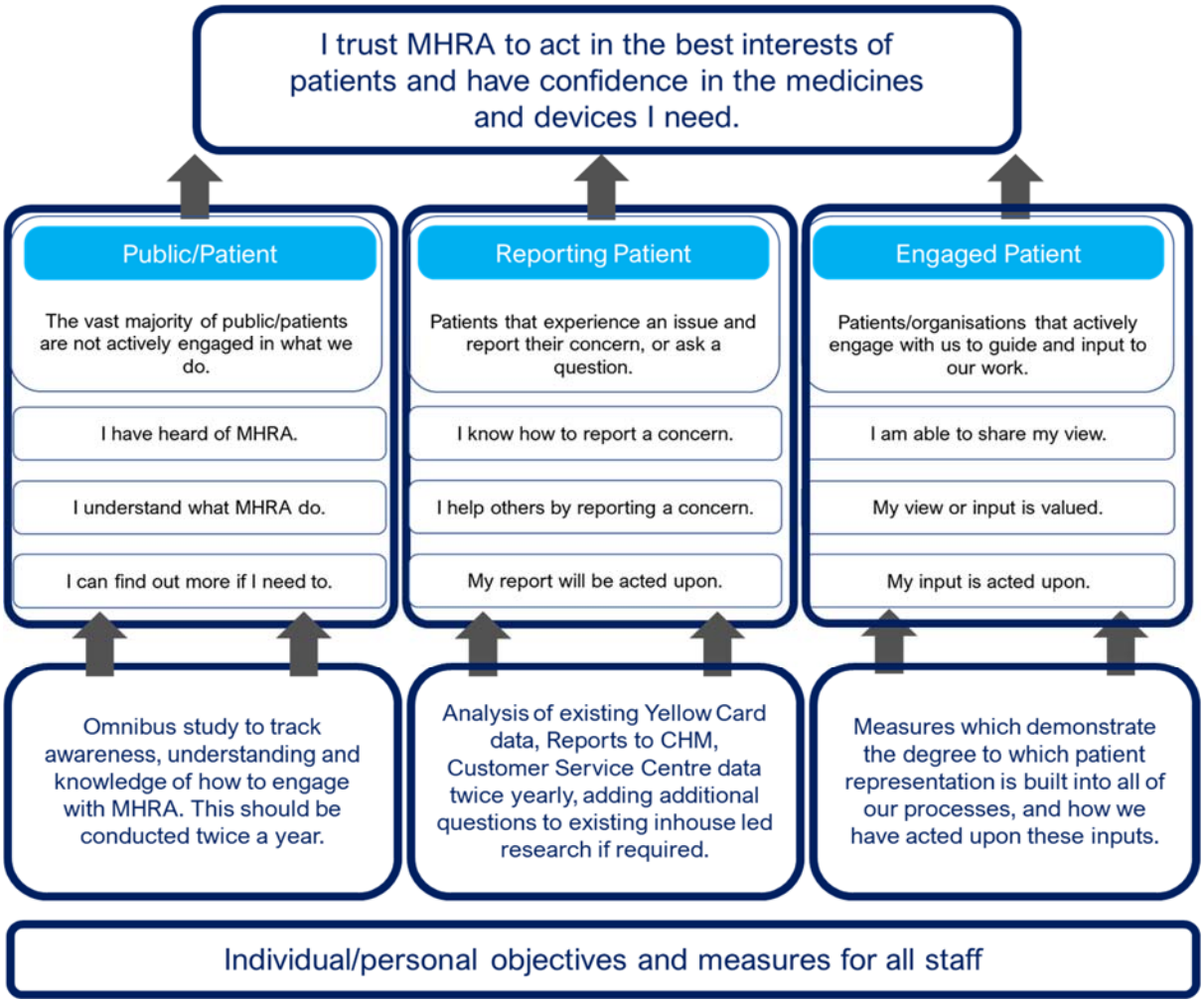
3.23 A public consultation on the appointment and operation of the new Patient Safety Commissioner has been launched and the Agency is keen to establish a strong and collaborative relationship with the Patient Safety Commissioner in due course.

4. Measuring the impact of the actions taken so far

4.1 The approach to measuring the impacts of the Agency's deliverables from the Cumberlege Review is under active consideration. It is clear that we need to measure a range of impacts, from the qualitative views of patients on how well their concerns have been listened to and addressed, to quantitative measures such as the timeliness of identification of harm from a medicine or medical device (eg speed of signal detection), robustness of risk evaluation (eg comparison with views of experts and/or of other regulators), extent to which patients' input has influenced the regulatory decision-making process, and importantly monitoring the impact of regulatory action on safety issues (has the risk been eliminated or reduced to a level which patients consider acceptable?).

4.2 As a key aspect of monitoring the impact of regulatory action, data from the Valproate Registry will enable us to monitor and track the usage of sodium valproate and compliance with risk minimisation measures as well as following the impact on any children who have been exposed to valproate before they were born.

4.3 In terms of measuring patient involvement, there does not appear to be any established methodology, so we propose to build a 'patient engagement index' so that we can monitor our progress. The diagram below sets out how our measurement of activity can be aligned to identifiable groups of patents, and how that in turn impacts upon public confidence and trust. We would use this assessment tool to build patient involvement into our processes. This could include the introduction of clear 'go/no go' decisions where further development cannot continue unless there is evidence of patient engagement at key points.



4.4 We propose to involve the IMMDSR Patient Reference Group on 29th July 2021 to obtain their early input on the kinds of impact measures this key group of patients, who have been extensively involved in providing evidence to the Cumberlege Review, will find meaningful. In addition, the Agency will carry out a further survey in Autumn 2021 to measure whether there is an improvement in the way that patients feel listened to and their views acted on.

5 Next steps

5.1 The Agency fully recognises that a change in our culture is a critical step to achieve the change that the Cumberlege Report said is needed. Early steps that we have taken to address cultural change include All Staff meetings and group work focussing on the shift from an internal science focus to an external outcome focus on the people we serve. The Organisational Development & Remuneration Committee has also been considering the Agency's work on culture and this is the subject of a separate paper to the Board.

6 Recommendation

6.1 Is the Board assured by the progress which the Agency is making in delivering the programme of actions to implement the recommendations of the Cumberlege Review?

6.2 The Board is invited to consider and comment on the evolving plans to monitor the impact of the deliverables and activities.

June Raine and Mercy Jeyasingham

Medicines & Healthcare products Regulatory Agency

BOARD MEETING HELD IN PUBLIC

20 July 2021

Title	What assurance can be provided by the Organisational Development and Remuneration Committee?
Board Sponsor	Anne-Toni Rodgers – NED & Chair Organisational Development and Remuneration Committee
Purpose of Paper	Assurance

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

1. Executive Summary

1.1 The Organisational Development and Remuneration Committee (ODRC) provides independent and objective advice to the Agency Board and the Chief Executive on their responsibilities relating to workforce planning, development and rewards at the Medicines and Healthcare products Regulatory Agency (MHRA); with the aim of developing a regulatory organisation which effectively delivers for patients, the public and other stakeholders.

1.2 On a regular basis it provides Assurance Reports on these topics to the Board.

2. Introduction

2.1 Given the MHRA's ongoing transformation programme the ODRC has continued to meet monthly. The Committee has recently considered the following and provides assurance/ recommendations to the Board as per Section 3.

- Transformation / Organisational Change - Progress to date.
- Transformation / Organisational Change: Function and Scale.
- Culture.
- Diversity & Inclusion.
- People Strategy.
- Executive Remuneration.
- Focus for ODRC.

2.2 The next meeting of the ODRC occurs on July 13th, after the deadline for July Board papers. It will consider the items listed below. The Chair of ODRC will provide the Board with a verbal update on key issues at its July meeting.

- **Transformation / Organisational Change MHRA: Function and Scale** - the detail of the MHRA's proposed high level deliverables indicating key expectations and deliverables for the MHRA in 2021/22.

- **Transformation / Organisational Change MHRA: Progress to date**

- **Executive Renumeration/Reward**

3. ODRC Assurance

Transformation / Organisational Change: Progress to date

3.1 The Committee routinely considers the Agency's Organisational Change timeline and progress to date. The Committee is, in the main, assured that progress has been made. We recognise that there has been an implementation delay and whilst disappointed that this delay will impact on the final date of implementation, we are currently assured that it will not impact the overall change deliverables and that

the Agency is on plan to deliver to its commitments by the revised deadline. A progress update will be considered at the July 13th meeting.

Transformation / Organisational Change: Function and Scale

3.2 Over the past months the Committee has reviewed and provided feedback on process and organisational structures as they developed. We are assured that the structure considered and approved by the Board in June will deliver an MHRA that is fit for purpose and will effectively deliver for patients, the public and other stakeholders. Implementation is considered under progress to date.

3.3 Detail of the MHRA's proposed high level deliverables indicating key expectations and deliverables for the MHRA in 2021/22 will be considered at the July 13th meeting.

Culture

3.4 The Committee considered the culture framework as it was developed and given the nature of MHRA transformation recommended a more disruptive approach to drive the behaviours we require for the new organisation to be successful.

3.5 The Committee felt that the transformation needs to bring about the change in behaviours and culture demonstrated within the Agency when faced with the challenges of COVID-19, for example: innovative, forward thinking, accountable, patient focused, delivering as One Agency, accelerating access whilst ensuring safety, maximising technology, effective and challenging leadership; and excellent communication.

3.6 The Committee is assured that much of the work underway, or in place, across the Agency including the Agency values, leadership focus, behaviours and branding supports a drive to change culture. It was agreed that the Executive would summarise the key changes that if delivered would signal a shift in Agency culture, the strategic drivers to make this happen and clear measures that would assure the Board that change had been delivered. This will be presented to the July Board for approval.

Diversity & Inclusion (D&I)

3.7 The Committee (joined by Mercy Jeyasingham as the Board D&I Champion) has reviewed the Agency's current position, its existing actions and plans vs Diversity and Inclusion. The plans are detailed and specific.

3.8 The committee:

- were pleased to note plans to increase and expand the apprenticeship programmes specifically looking at the science area and are assured that this will create opportunities to gain qualifications while working and target those from non-academic backgrounds and increase access from specific characteristic groups.

- discussed the use of BAME language and whether this was still useful. It was clear that this had also been discussed within the Agency. We are assured that this term remains useful for data purposes, however is not appropriate when considering detail.

- considered whether the Agency should be considering specific protected characteristic groups during transformation, in order to help achieve full potential. We are assured that this is not required, and the focus should be on initiatives already underway.

- asked for specific consideration as to how we can build diversity and ensure accountability of our Leaders to ensure diversity and inclusion. We are assured that we should expand what is already in place, for example: values and behaviours training for all managers; storytelling e.g. INsite blogs that staff can relate to; revisiting D&I networks across Agency and expanding plans to include identified actions such as Allyship. The Committee discussed the Civil Service success criteria and diversity in recruitment. The recruitment policy states the importance of diversity and inclusion and the available training. It was agreed that frequent reminders would be useful for those who are recruiting and would draw focus to the culture of the new organisation.

- considered how well staff networks are working within remote working and was assured that they are continuing to work well, with increased engagement and teams are building capabilities in existing networks to enable focus on newer ones. We will revisit the support we give to our networks and commitments made; to confirm resources required as we move forward.

- recognised the need to benchmark against other Arms-Length Bodies to understand what 'good' D&I looks like and was assured that networking & plans are in place to achieve this.

3.9 The Committee is assured that the Agency follows and effectively delivers a process and strategy in understanding and acting on Diversity and inclusion which is to cross-industry standards. The Committee asked the Executive to consider specific actions for the Board paper which will be reviewed at its July meeting.

People Strategy

3.10 The Committee has considered and reviewed the One Agency People Strategy. The Committee was pleased to note that the format of the document has been revised and simplified vs. previous People Strategies and its accessibility is much improved.

3.11 To support measurement and reporting the Committee asked for the action points to be drawn out under each high-level objective of the strategy. Top priorities were highlighted as leadership, attracting & retaining talent and managing people through change.

3.12 The Committee is assured that the Strategy will support effective delivery of the Transformation/ Organisational Change and will deliver for the MHRA as it moves forward.

Executive Remuneration Responsibilities & next steps

3.13 The ODRC will review the Executive reward and recognition award recommendations at its meeting on July 13th. Note: there is no Executive pay award this year due to the Civil Service pay freeze.

Other

3.14 The Committee has noted a behaviour whereby detailed spreadsheets are prepared to monitor activity against keys strategies. Whilst measuring action is absolutely key to delivering success; preparing spreadsheets that duplicate data captured in other reports; is time consuming and adds little value. It was agreed that the Executive would work to avoid duplicative and inefficient reporting.

Future work

3.15 The Committee has identified the following as a future/continued focus for its work:

- Organisational Change.
- Talent & Succession Planning.
- Executive Renumeration Decisions.
- Culture.
- Delivering One Agency.
- Executive /Management mentorship.
- Specific challenges as they may occur
- Diversity.

4. Recommendation

4.1 The Board is asked to note and consider this report and provide feedback.

Anne-Toni Rodgers (Chair ORDC)
20 July 2021

Medicines & Healthcare products Regulatory Agency

BOARD MEETING HELD IN PUBLIC

20 July 2021

Title	What are the strategic priorities for the development of culture and diversity to enable the Future Operating Model?
Board Sponsor	Jon Fundrey
Purpose of Paper	Strategic Direction

What are the strategic priorities for the development of culture and diversity to enable the Future Operating Model?

1. Executive Summary

1.1. To ensure the Agency transitions successfully to its Future Operating Model (FOM) and meets Delivery Plan outcomes, we are paying attention to our culture and within this to equality, diversity and inclusion (EDI). Culture is what brings diverse individuals together in the Agency to form our unique entity and the Agency relies on the different skills of its people and behaviours to influence and shape its culture.

1.2. Culture and EDI are key determinants of organisational effectiveness and essential components of a healthy organisation. The Agency's culture and EDI aspirations are set out in its Culture Action Plan and draft EDI Framework documents. These set the foundations for continuous improvement across these areas and the proposed steps will enable the FOM by leveraging the Agency's ability to attract and retain top talent to fuel innovation, embed patient centricity and drive better outcomes for patients and staff.

1.3. The business case for diversity is overwhelming[1] but although there is less tangible evidence to support the link between culture and improved business performance, experts agree it is essential to maintaining a productive workforce[2]. Both culture and EDI impact on staff engagement. When employees feel engaged with their job role or their organisation, they are not only likely to be happier, healthier and more fulfilled, but will likely deliver better performance, contribution and innovation[3].

1.4. This paper analyses the key issues and strategic priorities for the development of culture and EDI in the Agency and asks the Board to:

- Consider whether the recommended strategic culture and EDI priorities will enable the Future Operating Model and support the achievement of the 2021-2023 Delivery Plan objectives.
- Agree how Board Members will individually and collectively demonstrate Visible Allyship and commitment to EDI.

2. Introduction

2.1. People and culture issues have been recognised as the main factor behind the failure of many large-scale transformation programmes[4]. Culture is hard to define. It is not a static object that can easily be measured or a problem to be addressed, but a dynamic process to work with. One definition of workplace culture is "it is the character and personality of your organisation. It's made up of your organisation's leadership, values,

[1] The business case for diversity is now overwhelming. Here's why | World Economic Forum (weforum.org)
[2] What is Company Culture & Why It Matters: A Business Case | Arcoro HR
[3] Microsoft Word - The Evidence v 3d - BR4.docx (engageforsuccess.org)
[4] IPA Report on Getting It Right with People & Culture by EY

traditions and beliefs, and the behaviours and attitudes of the people in it[5]". Another is quite simply "How things are done around here[6]".

2.2. A modern definition of good diversity and inclusion is a workplace where: "people's differences are acknowledged, valued and used to enable everyone to thrive at work and where the organisation is representative of the population they serve. An inclusive working environment is one in which everyone feels that they belong without having to conform, that their contribution matters and they are able to perform to their full potential, no matter their background, identity or circumstances."[7]

Culture assessment and priorities

2.3. The Transformation Programme will revolutionise the ways the Agency delivers its business outcomes. Having a positive and inclusive workplace culture and a diverse and engaged workforce is vital to enable the FOM. All colleagues will be expected to do different things and/or do things in different ways and our challenge is to enable this.

2.4. Culture change only happens when peoples' behaviours change[8] and to support the transition to and consolidate our new operating model we developed a Culture Action Plan. (Delivery Plan objective: Develop an organisational culture action plan by Q1, 2021/22.) This sets out the Agency's desired culture, and actions towards achieving it and mitigates the strategic risk that the culture will not support future challenges.

2.5. How the transition is undertaken, (leaders' behaviours), will influence people's commitment to the new design, the quality of relationships across the Agency, and ultimately whether the new operating model will deliver its strategic aims. The Agency has a firm foundation to support behaviour change. In May 2020 a new Values and Behaviours framework (arrived at in consultation with over 800 staff) and an aspirational culture statement was introduced. Over half of those who responded (54.6%) to a Pulse Survey this year, thought these values and behaviours were likely or very likely, to help the agency change its culture to meet the new challenges and opportunities ahead. Nonetheless one of our priority actions is to align more closely the existing culture statement and **Values and Behaviours** Framework with the now further developed FOM.

2.6. Other key priorities to enable culture change are:

- Focus on **leadership and talent –** Senior Leaders need to be congruent, reliable and dependable in their messaging and behaviour, which will only be possible if they are fully committed to the transformation. Agency culture needs to enable the attraction and retention of talented people to enable the FOM. (Our use of success profiles means selection into leadership positions in the new structure will also consider evidence of role modelling the "right" behaviours and capability to develop required skills/behaviours.)

[5] Skills for Care
[6] Ouchi & Johnson,1978
[7] Inclusion and Diversity in the Workplace | Factsheets | CIPD
[8] *Behaviour is considered an immediate and reliable indicator of cultural understanding and assumptions.*

- Establishing a shared understanding about our **identity and vision, (**despite attempts to unite the three centres/cultures through the "One Agency – Delivering for Patients" vision statement, staff loyalty remains primarily to their "centre/division" and we use different wording to communicate our vision statement.)

- Changing mindsets, so **putting patients first** becomes the unconscious starting position for everything we do. (We are already on this journey.)

- Supporting people to "let go" of former ways and embrace the new ways of doing/being, (taking up new roles, renegotiating relationships and changing how they work together). In designing and embedding new ways of working (TP) we need to:
  - ensure new structures/job titles/systems/processes are integrated with our "to be" culture/values
  - ensure clarity on individual accountability, responsibilities and decision-making
  - define then provide the support that will enable people to work in a matrix way ("unleashing the "tiger in everyone")
  - invest in team building for new teams focussed on creating an inclusive and high-performance culture.

- Supporting colleagues to become more **innovative** and make risk-based (strategic) decisions. This will require an enabling culture of psychological safety. (Our current culture is risk conscious, which hampers innovation.)

- A commitment to develop a **learning organisation**[9] culture as this would enable all the priorities outlined above.

<u>EDI state of play assessment and priorities</u>

2.7. As a public authority, in addition to the foundation of legislative requirements, the Medicines and Healthcare products Regulatory Agency (the Agency) has a higher-level duty to have due regard to the need to:

- Eliminate unlawful discrimination, harassment, and victimisation
- Advance equality of opportunity
- Promote good relations between people who share a protected characteristic and those who do not

The Agency is therefore **committed** to:

Equality - of opportunity for all its employees, applicants, and potential applicants

Diversity – building a workforce which reflects the communities we serve and taking steps to ensure the Agency's expert committees and advisory boards do the same

[9] An organisation that continuously develops and learns from experiences – our successes and our failures – at an individual, collective and organisational level".

Inclusion – being amongst the most inclusive of organisations

and has similar responsibilities in respect of its' customers (especially patients and the public) in relation to equality and inclusion.

There are multiple assurance/reporting routes for EDI in the Agency and a new quarterly reporting process has been introduced by the Department of Health and Social Care (DHSC) as part of their duties to oversee their Arm's Length Bodies (ALBs). A diverse and inclusive workplace doesn't just have a positive impact on staff but it also leads to better service for our patients and partners.[10]

2.8. EDI is a golden thread which runs through and must be a key consideration in achieving our values (and linked behaviours). We are consulting relevant parties, for example the Inclusion network, on a new Agency EDI Framework for 2021 where we show the progress made on EDI actions and highlight the challenges faced. This Framework pulls together all of the Agency's EDI commitments into a single document making it easier to focus activity and track progress.

2.9. The EDI Framework priorities are[11]:

- **Leaders as champions of EDI and wellbeing:** To enable leaders to act as role models for inclusive behaviour, with a strong, public commitment to diversity and inclusion. (Investing in Leadership development is also a top Culture Action Plan priority.) The current overall RAG[12] rating is amber[13] for all three objectives in this priority.

- **Data and Indexes**: To build our data collection, analysis and reporting capability to support greater identification of D&I adverse impact/gaps across all parts of someone's career journey with the MHRA, (Medicines and Healthcare products Regulatory Agency). The current overall RAG rating is amber, (of the two objectives in this priority, one is amber/red and one is green.)

- **Recruitment and attraction:** Develop the Agency brand as an inclusive and diverse employer that looks at recruitment from root to stem and attracts people from all walks of life and backgrounds. The attraction and retention of talented people is vital to the Agency's future success and our approach will improve diversity of thought, resulting in better outcomes. The current overall RAG rating is amber, (of the five objectives in this priority one is red, three are amber and one is green).

[10] Nathan, M., & Lee, N. (2013). Cultural Diversity, Innovation, and Entrepreneurship: Firm-level Evidence from London. Economic Geography, 89(4), 367-394.; Díaz-García, C., González-Moreno,

[11] Each priority has been chosen where there has been evidence to show it has either been successful in other similar organisations, it is a Civil Service priority or there is evidence in our Agency data.

[12] The Agency uses a traffic light system (red, amber , green RAG) to assess risk

[13] We have several objectives within each area of work thus we are giving an overall or average rating for the whole area. Each objective has several actions, outcomes and success measures. As the Framework has been made for 2021 (Financial year), we have assessed each action on whether it has been started, completed or underway and whether the desired outcome/impact has been achieved.

- **Everyone to achieve their full potential through talent and learning opportunities:** We will foster an environment of creation and innovation. (This is reflected in the Culture Action Plan where developing innovation capability is key to ensuring improved outcomes for patients.) The current overall RAG rating is green, (of the four objectives in this priority, one is amber and three are green.)

- **Inclusive Culture and Behaviours:** everyone to feel like they belong in the Agency. A psychologically safe and open culture, where good relations are fostered between all colleagues and intolerant behaviour is called out. This aligns with the Culture Action Plan. – Current overall RAG rating is green/amber, (of the ten objectives in this priority four are amber and six are green).

- **Public Sector Equality Duty:** our work, whether internally or externally facing must meet our duties under the Public Sector Equality Duty.[14]We will carry on building on protocols already in place in order to ensure that we are meeting our obligations – Current overall RAG rating is amber. (There is one objective for this priority.

3. Proposal

Culture

3.1. The Culture Action Plan identifies high-level interventions to enable culture change for each strategic priority, signposting where activities will be delivered via existing (Divisional) Business Plans. (The Board is asked to note that aspiring to be a learning organisation, will help contribute towards addressing all our cultural challenges and to be assured actions are already being progressed through Agency business plans/strategies to improve on patient engagement, leadership, inclusion and wellbeing and use of new technology.)

3.2. It will be a dynamic plan, reflecting that culture is complex and constantly shifting. This means interventions will be regularly refreshed and evaluated to ensure we are utilising the best intervention(s) for any given set of circumstances and assessing the impact of the intervention(s). A Working Group, (led by the Human Resources (HR) Division with membership from Communications Division and Technology-Digital, Data, Delivery (TD3) and an open invitation to Staff Partnership Committee) has been set up to oversee this.

3.3. Given the nature of culture, it is not possible to measure it with precision but by accessing a mix of hard and soft data we will be able to show the progress we are making towards our “To Be” culture. We are currently participating in the CS Culture Survey and the data from this, as well as data from last year’s People Survey, our internal pulse surveys, and data we hold from our Values’ development work, will allow us us to set a robust benchmark. Using culture enquiry methodology[15] at regular

[14] equality-duty.pdf (publishing.service.gov.uk)

[15] Culture Enquiry is: (1) a means of individuals and groups gaining insight into the culture they work in and an invitation to develop it and (2) feeding back to leaders insights into cultural patterns that either currently exist or are emerging.

intervals, will allow us to keep track of how culture is changing at a macro and micro level.

3.4. The Agency's predominant culture is "Safety and Order"[16] so, to develop a culture of being innovative and forward thinking, will require a change in how we learn. (Consideration will be given to whether external support is required to move this forward, and any related business case progressed.)

3.5. Although culture is everyone's responsibility because of their power and visibility, leaders have a greater impact on culture than others. Therefore, we are prioritising leadership development, including Board development, to help develop the skills and behaviours that will enable the Agency's success. The impact of the Culture Action Plan and EDI Framework on the FOM will be determined by the extent to which leaders' role model the Agency's values and always display the right behaviours. Our proposals for developing leaders include interventions to raise their self-awareness so, we will be rolling out 360' feedback for all leaders below Senior Civil Service[17],(SCS), investing in developing leadership teams and creating opportunities to reflect on their own leadership style.

3.6. By enquiring into culture patterns within leadership teams, we will be able to show any gap between the desired culture and the reality. By making this visible, leaders will have a choice regarding what they do and how they continue to behave. Peer pressure (in the broadest definition), with encouragement of constructive feedback and where necessary our Performance Management system, which is aligned to behaviours and values, should address poor behaviours and reward the desired behaviours.

EDI

3.7. Research shows that diverse teams bring an advantage in relation to increased customer insight, (insight that will help us meet the needs of a diverse population that is constantly changing) and that:

- Employees who feel valued are more likely to be engaged with their work[18], and inclusivity increases productivity in the workplace[19];
- Diverse views around the table lead to more innovation[20] and new ideas; and
- Greater diversity and inclusion enhance opportunities to attract and retain great people.

[16] The Leader's Guide to Corporate Culture (hbr.org)
[17] 360' already in place for SCS
[18] Rhoades, L., & Eisenberger, R. (2002). Perceived organizational support: a review of the literature. Journal of Applied Psychology, 87, 698-714.
[19] Harter, J. K., Schmidt, F. L., & Keyes, C. L. (2003). Well-being in the workplace and its relationship to business outcomes: A review of the Gallup studies. Flourishing: Positive psychology and the life well-lived, 2, 205-224.
[20] Nathan, M., & Lee, N. (2013). Cultural Diversity, Innovation, and Entrepreneurship: Firm-level Evidence from London. Economic Geography, 89(4), 367-394.; Díaz-García, C., González-Moreno, A., & Jose Sáez-Martínez, F. (2013). Gender diversity within R&D teams: Its impact on radicalness of innovation. Innovation, 15(2), 149-160.

3.8. For the benefits of diversity to be felt, we are prioritising an inclusive culture, where all our employees feel they can bring their authentic self to work and feel valued for the distinctive perspective they bring. Such an environment can only be created where there is equality of opportunity for all, active inclusion of all and perceived and real barriers to this are identified and removed. This type of environment is vital for the FOM and the Agency's future success.

3.9. The EDI Framework and actions we are taking on the People Survey data and feedback alone, may not be enough to create the inclusive environment this Agency will need during the transformation and for the future. Therefore, we propose the launch of an additional Allyship strategy to further foster inclusion, authenticity, and work towards a more psychologically safe environment. The proposal includes these five things:

1) Visible Allyship[21]: In addition to Mercy Jeyasingham's role as the Board EDI Champion, the Agency wants to have a senior leader champion for each of the diversity strands (champions identified where already in place) and become members of the Staff Inclusion Group meetings[22]:
    - Age
    - Race
    - Disability
    - Religion/Faith
    - LGBT+
    - Social Mobility (John Quinn, Acting Chief Technology Officer)
    - Gender
    - Mental Health/wellbeing – (Sam Atkinson, Acting Chief Quality and Access Officer)
2) Every member of the Senior Civil Service (SCS) signs up to be reverse mentored by someone who shares a different protected characteristic to them[23]
3) Every member of the SCS creates a pledge towards EDI to be shared on Agency's Intranet (INsite) and with their teams.
4) Accountability: Senior leaders ask questions about EDI when reviewing policies and papers as well as act as the critical friend of the Diversity and Staff Engagement Team by asking them the difficult questions.
5) EDI learning as part of SCS and new Board member induction, to ensure that all leaders are aware of the Agency's commitment to EDI and their responsibilities for making the EDI Framework a reality.

[21] Allyship is about building relationships of trust, consistency and accountability with marginalised individuals and/or groups of people. Although you might not be a member of an underinvested or oppressed group, you can support them and make the effort to understand their struggle and use your voice alongside theirs. NHS England » Allyship

[22] Meetings are held monthly for 1h, we would propose a senior leader come every quarter

[23] Reverse mentoring is when someone from a more junior grade mentors someone senior. It is a learning opportunity for the senior leader and a development opportunity for the junior colleague. It would take approximately 1h a month. Here are the benefits: Reverse mentoring: seeing things differently - Civil Service (blog.gov.uk)

4. Recommendation

4.1. EDI is everyone's responsibility but can fall to the bottom of the to-do list when things get busy. The Board is invited to make a visible commitment to EDI so that we can keep driving forward this agenda with momentum to build the inclusive environment that we are striving for.

4.2. The Board is asked to:

- Consider whether the recommended strategic culture and EDI priorities will enable the Future Operating Model and support the achievement of the 2021-2023 Delivery Plan objectives.

- Agree how Board Members will individually and collectively demonstrate Visible Allyship and commitment to EDI.

Jon Fundrey
20 July 2021

Medicines & Healthcare products Regulatory Agency

BOARD MEETING HELD IN PUBLIC

20 July 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 This report sets out the Audit and Risk Assurance Committee's (ARAC) response to two actions assigned to it by the Board and summarises key outcomes from ARAC's meetings on 28 May and 14 June.

2. Board Action: Financial sustainability - ARAC to consider best and worst-case scenarios for the next two years.

2.1 ARAC received a detailed presentation on the Agency's projected financial position for the three years 2021-22 to 2023-24 with and without cost savings. The worst-case scenario (the Agency has a sustained deficit) would arise should the Agency not be taking action to reduce its costs. ARAC was assured that successful implementation of the Agency's transformation programme financed from its reserves to restructure staffing, modernise its digital legacy systems and reduce its corporate costs should mitigate the risk of a sustained deficit while remaining an effective Regulator in safeguarding public health. In addition, financial resilience should be further strengthened following the implementation of the findings of the Agency's fees review currently underway. This should ensure that the Agency's fees accurately reflect its revised cost base following transformation.

2.2 We were assured that the Agency has reliable financial plans in place. This is however an ambitious time-critical programme which requires careful management and monitoring with the flexibility to take remedial action quickly if needed. ARAC will review the Agency's mid-year financial position and seek assurance on progress in securing the necessary cost reductions together with the implications for 2021-22 as a whole and future years at its autumn meeting.

3. Board Action: Review lessons learned from Driver and Vehicle Licensing Agency experience in ceasing to be a Trading Fund

3.1 As a result of reclassification by the Office of National Statistics, the MHRA ceases from 1 April 2022 to be a Trading Fund and becomes part of the Department of Health and Social Care's financial management and control framework. In order to be confident that the Agency has plans to manage the transition effectively and to understand the potential consequences for financial sustainability we were pleased to receive a presentation from the Chief Financial Officer of the Driver and Vehicle Licensing Agency (DVLA) which until recently was also a Trading Fund.

3.2 We concluded that DVLA's experience indicated three key lessons:

(1) enhanced oversight by the host Department will increase the need for more frequent and granular reporting by finance and line managers across the Agency;

(2) no longer having the freedom to use financial reserves to fund investments will mean the Agency will have to rely on the host Department for additional funding requiring longer term investment plans underpinned by well-developed business cases; and

(3) the scale of changes involved with the transition from Trading Fund status merited this being managed as a significant project with appropriate governance.

4. Other issues covered by the Committee

Finalisation of the Agency's Annual Report and financial statements for 2020-21

4.1 The Board approved the MHRA's Annual Report and Financial Statements 2020-21 in principle at its meeting on 15 June. There remained a number of accounting issues which needed to be resolved. The Board delegated responsibility to the ARAC Chair for ensuring that these were satisfactorily dealt with so the Accounting Officer, Dr Raine, could sign the financial statements. As at 6 July we were awaiting formal approval by the Treasury for the provision of the undercharge of VAT by CPRD included in the financial statements. External Audit have also said that they are now reviewing their requirement from previous years as to how the Agency accounts for CPRD. This will be resolved shortly. The Agency should still present its Annual Report and Financial Statements to Parliament as required before the Summer Recess. The Comptroller and Auditor General is still expected to give a clear audit opinion.

4.2 As part of its review of the Agency's Financial Statements and Annual Report ARAC considered: the Agency's overall financial performance for 2020-21; Internal Audit's annual assurance report (including three final specific reports as part of its 2020-21 programme of work); the Agency's Governance Statement together with an update on the risk register; and the report of the external auditors.

Financial Performance for 2020-21

4.3 Financial performance for 2020-21 was broadly as expected (reported to the Board at its 15 June meeting). ARAC sought assurance that the financial statements reflected the considerable work which the Agency and in particular the National Institute for Biological Standards had contributed to the successful roll out of the COVID vaccines. This is explained in the narrative of the Annual Report.

4.4 ARAC paid tribute to the work which Boryana Stambolova and Salim Master and their colleagues in Finance had done to produce the financial statements to an accelerated timetable. ARAC thanked Boryana for her considerable contribution to the Agency and wished her well in her new role at NICE.

Internal Audit

4.5 We considered three final internal audit reports for 2020-21: Cyber Security (moderate assurance); legacy replacement (moderate assurance); Customer Service Centre (split assurance - substantial and limited explained in paragraphs 4.6 and 4.7 below).

4.6 The MHRA established the Customer Service Centre as a means to improve how the public can engage with the Agency while at the same time reducing costs. Internal Audit found that for those services which now operated as part of the Centre, including overall performance management and improvements in customer satisfaction, justified a substantive assurance rating.

4.7 While the original business case had assumed that all of the Agency's services involving some interaction with the public would be through the Customer Service Centre, Internal Audit found that only 60 percent were being delivered in this way. Volume had increased as the majority of the public's interaction with the Agency on COVID-19 was through the Centre. Nevertheless Internal Audit awarded limited assurance as the reduced scope of the project meant that none of the planned cost savings have been realised reflecting a more systemic need to improve project implementation. We were given assurance that lessons highlighted by Internal Audit and the Agency's own review were being implemented as part of the MHRA's current transformation programme.

4.8 We reviewed Internal Audit's annual report which provided independent evidence on the effectiveness of the MHRA's systems of control, governance and risk management in 2020-21. Internal Audit based their assurance on 12 reviews and of these: one received substantial assurance; eight received moderate assurance and three were awarded limited assurance. In the previous year with 10 reviews, only one received limited assurance and we sought confirmation that the increase in 2020-21 was not evidence of a weakening of financial control. We were assured that the circumstances justifying the three limited assessments were specific to the areas examined and not systemic. On this basis and as for the previous year, Internal Audit awarded the Agency an overall moderate assurance rating confirming that it had in place adequate and effective systems of control, governance and risk management in 2020-21.

4.9 Internal Audit recognised the positive changes which the MHRA has underway arising from its Governance Review and the enhancement of key systems such as business planning. Internal Audit helpfully highlighted a number of systemic issues arising from its work which it recommended that the Agency should focus on as part of its transformation programme. These were: leadership including challenging the affordability of programmes and making timely decisions; performance management including having an appropriate balance of outcome and input measures; and having oversight and monitoring of agreed action plans and the realisation of intended benefits. Dr Raine welcomed these insights and emphasised that implementing them was integral to the managerial and cultural change underway in the Agency. ARAC asked Internal Audit to review general

progress as they implemented their programme of reviews in 2021-22. We also emphasised the importance of Internal Audit adding value to the Agency through its professional expertise and cross-government insights of good management practice.

Governance Statement and risks

4.10 We reviewed and endorsed the Governance Statement which is published with the Annual Report. This sets out the arrangements that the Agency had in place in 2020-21 to ensure that its resources and information assets were used appropriately. We noted that the Governance Statement had improved compared to previous years particularly in setting out concisely the action taken to implement the Governance Review. We also drew on the independent assurance provided by Internal Audit that there was no evidence of diminution in financial control arising from the new senior management structure and associated changes in responsibilities.

4.11 As the Agency's transformation programme is fully implemented over the next six months it will be important for the Executive and the Board to have confidence that the new arrangements and their underlying governance are operating effectively. The MHRA's newly established Governance Office will be revisiting the Agency's assurance framework which should include a comprehensive map of how the flow of management information and other data provides ongoing assurance over for example, financial management and control; value for money in the way resources are used; and information security. ARAC will review the revised framework in early 2022 and report to the Board next February.

4.12 We reviewed the risk register and were assured that risks were comprehensively covered. We were pleased to see that some risks had been de-escalated indicating that the risk register is being used dynamically in helping ensure that management action and resources are prioritised appropriately .We have reported before that the Agency's approach to risk management has improved considerably in recent years. Building on this we recommend that there is still scope to consolidate some risks further to show the interdependencies which could impact adversely on strategic priorities such as maintaining the reputation of the Agency, public confidence and the quality and completeness of data evidence underpinning regulatory decisions. Some risks are more time limited and it would help to provide an estimate of when they are likely to be managed down to an acceptable level. We support the new Governance Office in its drive through training and wider cultural change to help ensure the consistent application of good risk management throughout the Agency.

External Audit

4.13 We received external audit's report which summarised their findings arising from the audit of the MHRA's Financial Statements for 2020-21. We discussed the need to disclose and explain separately the provision for the undercharge of VAT by CPRD (brought to the Board's attention at its 15 June meeting) and the need to have regulatory approval for this from the Department of Health and Social Care and the Treasury. We endorsed a paper presented by the Executive and required

by the auditors confirming that the MHRA remained a going concern over the remaining period that it remained a Trading Fund. We sought assurance and were given an explanation over the value of CPRD's cash balances and their disclosure.

4.14 As in previous years Finance and the new Governance Office will hold a lessons learned review with the NAO which ARAC will consider at its next meeting.

Michael Whitehouse
6 July 2021