Medicines & Healthcare products Regulatory Agency

AGENDA FOR BOARD MEETING HELD IN PUBLIC

1:30 pm – 4:00 pm on Tuesday 21 June 2022

Chair: Stephen Lightfoot

	AGENDA ITEM	PURPOSE	PRESENTER
1:30	INTRODUCTION		
	1. What is the purpose of this meeting, who are the Board Directors and are there any absences?	Information	Chair
	2. Are there any new Declarations of Interest?	Information	All
	3. What were the minutes and actions from the last meeting?	Approval	Chair
	AGENCY PERFORMANCE		
1:45	4. How much of the MHRA Delivery Plan was delivered in the first year of 2021/22?	Assurance	June Raine
2:05	5. What Assurance can be provided by the Audit and Risk Assurance Committee?	Assurance	Michael Whitehouse
2:20	6. What were the financial results of the MHRA in 2021/22?	Assurance	Joann Passingham
2:35	7. How will the performance and governance of the MHRA be reflected in the 2021/22 Annual Report?	Approval	Carly McGurry
	OPERATING CONTEXT		
2:50	8. What are the most important current activities and priorities from the CEO's point of view?	Context	June Raine
	GOVERNANCE		
3:10	9. What are the key requirements of the MHRA in the proposed new Framework Agreement with DHSC?	Endorsement	Carly McGurry

	PATIENT SAFETY		
3:20	10. What are the key priorities in the MHRA Enforcement Strategy and how does this help keep patients safe?	Assurance	Alison Cave
	EXTERNAL PERSPECTIVE		
3:40	11. What questions do members of the public have about the items on this Board Meeting Agenda?	Public Engagement	Chair
4:00	CLOSE OF MEETING	-	Chair

MHRA Board Declarations of Interest – June 2022

The MHRA Board is responsible for advising and agreeing the strategic direction of the Agency, endorsing the Agency's recommendations to Ministers on key financial and performance targets, and advising on and monitoring plans to ensure those targets are met.

The Board supports the Chief Executive Officer in the effective delivery of services and overall performance by providing leadership, developing strategy, advising on the delivery of policies, maintaining high standards of corporate governance, scrutinising performance and ensuring that controls are in place to manage risk.

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

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

Name and MHRA Role	Name of Other Company or Organisation	Nature of interest	Paid	Current
Amanda Calvert Non-Executive Director	Astrazeneca	Ex-employee shareholder Immediate family member	No	Yes
	Quince Consultancy Ltd	Provides consultancy services including companies in the healthcare sector.	Yes	Yes
	Athenex Pharma	Quince Consultancy providing strategic consultancy on oral oncology chemotherapy platform. ILAP applicant and Marketing Authorisation applicant.	Yes	Yes
	University of Manchester digital Experimental Cancer Medicine Team	Quince Consultancy providing strategy and data protection consultancy	Yes	No
	Cambridge Judge Business School	Member of Advisory Board	No	Yes
	The Guinness Partnership Limited – Housing Association	Non-executive Director, member of Audit Committee and Chair of Health and Safety Committee	Yes	Yes
Dr Alison Cave Chief Safety Officer	None	N/A	N/A	N/A
Dr Paul Goldsmith Non-Executive Director	Closed Loop Medicine Ltd	Shareholder, director & employee; ILAP applicant and user of CPRD	Yes	Yes
	Summit Inc	Shareholder	No	Yes
	Ieso Digital Health	Shareholder	No	Yes
	MDU Ltd	Director	Yes	Yes
	MDU Investments Ltd	Director	Yes	Yes
	NHS	Consultant Neurologist	Yes	Yes
	NHS	Clinical Senate Member	No	Yes
	Big Tent Foundation	Trustee	No	Yes
	Radix Group Limited	Trustee	No	Yes
	Sleepstation	Co-founder of original programme, 2012-2014	No	No
Professor Graham Cooke Non-Executive Director and Deputy Chair	30 Technology Ltd	Consultant/Advisor	Yes	Yes
	DNAnudge Ltd	Consultant/Advisor	No	Yes
	Seventh Sense Biosystems	Consultant/Advisor	Yes	Yes
	Debevoise and Plimpton LLP	Consultant/Advisor in relation to COVID protocols	Yes	No
	Sanofi CoV	Chair of End Point Review Committee for vaccine trial	Yes	Yes
	WHO	Chair of Committee for Selection and Use of Essential Medicines	No	Yes
	NIHR	NIHR Research Professor	Yes	Yes
Claire Harrison Chief Technology Officer	None	N/A	N/A	N/A

Name and MHRA Role	Name of Other Company or Organisation	Nature of interest	Paid	Current
Haider Husain Associate Non-Executive Director	Healthinnova Limited	Chief Operating Officer	Yes	Yes
	Milton Keynes University Hospital NHS Foundation Trust	Non-Executive Director	Yes	Yes
	British Standards Institute	Panel Chair BS30440 – Use of AI within Healthcare	No	Yes
	Dementia Carers Count	Trustee	No	Yes
	World Ward Muslim Memorial Trust	Trustee	No	Yes
	Microsoft Corp	Shareholder	Yes	Yes
	BBC	Family Member	No	Yes
	NHS Buckinghamshire, Oxfordshire and Berkshire West Integrated Care Board	Associate Non-Executive Director	Yes	Yes
Mercy Jeyasingham MBE Non-Executive Director	Royal College of Podiatry	Consultancy	Yes	No
	NHS South West London Integrated Care Board	Non-Executive Member	Yes	Yes
Raj Long Non-Executive Director	Gates Foundation	Employee – Deputy Director	Yes	Yes
	Bristol-Myers Squibb	Ex-Employee Shareholder	Yes	Yes
	RESOLVE (Sustainable solutions to critical social, health, and environmental challenges)	Scientific Advisory	No	Yes
	Novartis	Ex-Employee Shareholder	Yes	Yes
	EC IMI NEURONET EC Innovative Medicines Initiative (IMI) Non-Product	Scientist Advisory Board	No	Yes
	Gates Venture – EC Innovative Medicines Initiative (IMI) Non-Product – IMI European platform for Neurodegenerative Disorders	Advisory	Yes	Yes
	HUYA Bio	Access Advisory	Yes	No
	PAVIA – PV Africa Board (EC Funded)	Advisory Board	No	Yes
	WHO – Sustainable COVAX Manufacturing Strategy for Regional Health Security	Advisory Expert	No	Yes
	UK Health Security Agency	Associate Non-Executive Board Member	Yes	Yes
Jo Passingham Interim Chief Financial Officer	None	N/A	N/A	N/A
Laura Squire OBE Chief Healthcare Quality & Access Officer	None	N/A	N/A	N/A

Name and MHRA Role	Name of Other Company or Organisation	Nature of interest	Paid	Current
Michael Whitehouse OBE Non-Executive Director	South East Coast Ambulance Services NHS Foundation Trust	Deputy Chair & Senior Independent Non-Executive Director Chair of Audit Committee Chair of Charities Committee	Yes	Yes
	Cruse Bereavement Charity	Trustee Chair of Finance and Audit Committee	No	No
	Republic of Ireland Audit Office	Member of Audit Committee	No	Yes
	National Audit Office	Board Member and Chief Operating Officer until 17 April 2017	No	No
Glenn Wells Chief Partnerships Officer	None	N/A	N/A	N/A

Medicines and Healthcare products Regulatory Agency

Minutes of the Board Meeting Held in Public on 19 April 2022

(11:00 – 13:30)

Round Room, MHRA, 10 South Colonnade, E14 4PU; and by Zoom Webinar

Present:

The Board

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

Others in attendance

Rachel Bosworth	Director of Communications, MHRA
Natalie Richards	Head of the Executive Office, MHRA
Helen Lovell	Deputy Director, Medicines Regulation and Prescribing, DHSC

INTRODUCTION

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

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

1.2 The Chair informed all attendees that due to the large number of questions received ahead of each Board meeting held in public, from April 2022 onwards the Board will only answer questions during the meeting related to the substantive items on the agenda; all other questions will be answered in writing.

Item 2: Are there any Apologies or Declarations of Interest

2.1 Apologies were received from Claire Harrison, Chief Technology Officer; Carly McGurry, Director of Governance; Alison Strath, Chief Pharmaceutical Officer for Scotland; Greig Chalmers, Head of Chief Medical Officer's Policy Division in the Scottish Government, and Cathy Harrison, Chief Pharmaceutical Officer for Northern Ireland.

2.2 The Board reviewed the Declarations of Interest for all MHRA Board members. Paul Goldsmith declared an additional declaration to those currently recorded; Closed Loop Medicine has submitted an ILAP application. The CEO's report describes research work on polio eradication and funding from the Bill and Melinda Gates Foundation and collaboration with Imperial College; it was confirmed that neither Raj Long nor Graham Cooke had any involvement with this work. The CEO's report also described work with the National Institute for Health and Care Research (NIHR); it was confirmed that Graham Cooke has not had any involvement in this work. The Chair was satisfied that there were no conflicts of interest preventing any of the NEDs from participating in the full agenda of this meeting.

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

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

AGENCY PERFORMANCE

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

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

(i) Healthcare Access – including latest updates on clinical trials; the Early Access to Medicines Scheme (EAMS); the consultation on the future regulation of medical devices; COVID-19 vaccines and therapeutics; COVID-19 vaccine independent batch release testing; SARS-CoV-2 RNA detection in wastewater; medicines licensing; Project Orbis; enabling continuous medicines and vaccine supply; measuring the impact of data institutes; and publication of updated GMP/GDP guidance;

(ii) Partnerships – including updates on medicines advertising regulation; a long COVID study with the NIHR; the Agency's role in Global Pandemic Preparedness; working with other organisations to support vaccine development; working towards global polio eradication; good practice symposia; and international engagement;

(iii) Patient Safety – including updates on the SafetyConnect system; expert advice on medical devices; medical devices safety issues; a safety review on paracetamol and hypertension; COVID-19 testing; and the Agency's Criminal Enforcement Unit;

(iv) Patient Involvement – including an update on the safety review of isotretinoin;

(v) Dynamic Organisation – including an update on the Transformation Programme; and

(vi) Financial Sustainability – including an update on financial sustainability.

4.2 The Board thanked Dr Raine for her report and provided comments relating to the success of the SafetyConnect project; the hard work of Agency staff for continued delivery through the transformation; how the MHRA can take forward the recommendations in the Goldacre report; the importance of patient involvement as a tool in clinical trials and throughout the ILAP process; how to improve diversity in clinical trial applicants; the consultation on medical devices legislation; the One Agency Leadership Group and work in the Agency to understand the benefits of transformation and to develop leaders of the future.

4.3 The Board provided further comments regarding filling of vacancies; transitioning from the work done throughout the pandemic to business as usual and how to learn from this work; and how to improve the Agency's performance above pre-pandemic levels via changes to improve processes.

PATIENT SAFETY

Item 5: What assurance can be provided by our Patient Safety & Engagement Committee?

5.1 The Board considered the assurance report from the Patient Safety & Engagement Committee (PSEC). The PSEC had considered principles for consultations; complaints' handling standards and procedures; risk perception in patients; and the results of the public engagement on the Yellow Card Biobank. The Board noted the update and provided comments regarding risk communication; the Yellow Card Biobank and working with the Citizens Jury to gain a broad representation of the UK population; seeking more information from the Parliamentary Ombudsman in managing complaints; an action was taken to consider whether complaints which are escalated to the Parliamentary Ombudsman should be reported to the Board.

Action 78: Consider whether complaints escalated to the Parliamentary Ombudsman should be reported to the Board ***Rachel Bosworth***

5.2 The Board provided further comments regarding improving patient information leaflets and information to patients; utilising different forms of media to communicate to patients including utilising video formats; how to ensure the public understands how the MHRA takes benefit-risk decisions; and development of further opportunities for the Yellow Card Biobank by linking with partners. The Board was assured that the PSEC is carefully considering these issues.

Action 79: Hold a discussion on the Yellow Card Biobank at an upcoming Board meeting ***Alison Cave***

DYNAMIC ORGANISATION

Item 6: What assurance can be provided by our Organisational Development & Remuneration Committee?

6.1 The Board considered the assurance report from the Organisational Development & Remuneration Committee (ODRC). The ODRC had considered Agency progress on the recruitment of people to roles in the new organisation; a review of the design proposals to deliver key services that will enable the Agency to deliver on its objectives; the progress of the leadership and culture plans to support the development of the new organisation and operating model; and a review of the progress made to deliver the recommendations from the internal audit of culture.

6.2 The Board noted the report and provided comments on the importance of finalising the placement of employed staff into posts in the new organisation; considering the use of reskilling programmes for staff who have been partially matched; and utilising a new approach to recruitment. The Board noted the ODRC assurance report with thanks.

Item 7: What assurance can be provided by our Audit & Risk Assurance Committee?

7.1 The Board considered the assurance report from the Audit & Risk Assurance Committee (ARAC). The ARAC considered four Internal Audit reports on Safety Connect; Implementation of the recommendations from the Independent Medicines and Medical Devices Safety Review; Order to Cash; and Preparedness for the Change in the Agency's Trading Fund Status. ARAC also considered a paper from Human Resources on payroll controls and reviewed the implications of the findings of this work for the Accounting Officer's Annual Governance Statement for 2021/22 which is published as part of the Annual Report. Finally, the ARAC made a number of recommendations for Internal Audit's proposed work programme for 2022/23.

7.2 The Board noted the report and provided comments regarding the proposed action plan to address the issues on the Order to Cash internal audit report; process improvement and training for staff to address issues identified through the audits; improvement work on customer records; replacing the management information system to move away from manual interfaces; working with the auditors on the 2021/22 accounts; and the proactive approach the team are taking to progress areas where improvements were identified in internal audit reports.

FINANCIAL SUSTAINABILITY

Item 8: What are our financial plans for the Agency to achieve financial sustainability in 2022/23?

8.1 The Board considered a proposed budget that will enable the MHRA to deliver all of our services and the work outlined in the second year of our Delivery Plan. It was noted that the budget has a deficit of £0.7million, which means that we will have pressure within our budget of less than 0.5% at the beginning of the year. The Executive Committee has agreed that this pressure will be managed in-year to balance the budget by the end of the financial year.

8.2 The Board thanked all the team involved in developing this balanced budget. As the Agency is no longer a trading fund it will be vital to manage the Agency's finances within the agreed budget. The Board also thanked DHSC colleagues in working with MHRA on the development of this budget. The Board provided further comments regarding the importance of the Agency making investments in new systems and in people; ensuring the Agency recovers costs of system investments to address legacy system debt; forecasting income patterns; ensuring appropriate resources are dedicated to patient engagement; optimising scientific capital spending; and continuing to work with external partners to maximise benefits to patients.

8.3 The Board approved the budget with the caveat that the deficit must be balanced by the end of the financial year.

Action 80: Implement the Budget as approved by the Board for 2022/23. Ensure the deficit is balanced by end of the year. ***Jo Passingham***

EXTERNAL PERSPECTIVE

Item 9: How are we going to provide more opportunities for public engagement with the Agency?

9.1 The Board considered a paper recommending the provision of more opportunities for public engagement with the Agency. The Board noted there has been a significant increase in the Agency's engagement with patients and public over the last twelve months, and the Patient Involvement Strategy has been a key driver of this change. However, there is still more that could be done to further develop our engagement approaches, in particular focusing on how the Agency can receive a diverse range of inputs from all sectors of the communities we serve.

9.2 The Board reviewed updates on some of the progress achieved over the last year and the proposal to gather more insight from patients, particularly from those groups the Agency engages with less, as the basis for further engagement. It was noted that the input of the PSEC will be sought when developing this work.

9.3 The Board supported the proposal and noted that Implementing these public involvement activities is an important step in building and maintaining public trust; focusing on equality, diversity and inclusion specifically relating to health literacy; working across the health system including health observatories; enhancing our digital capability; building in accountability for industry to undertake patient engagement and

involvement in their development processes; creating a meaningful outcome-based set of tools to use systematically; ensuring healthcare professionals are included in this work as the first point of contact to patients, noting there is a consultation in development in this area; developing a dashboard of all the touchpoints the MHRA has with patients and healthcare professionals to enable any gaps to be identified; and the scale of the patient engagement work the MHRA has initiated following the Cumberlege Review.

Action 81: Continue to progress the work on the evolving approach to patient and public engagement; implement the changes to public questions at the Board
Rachel Bosworth

EXTERNAL PERSPECTIVE

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

10.1 The Board answered a range of questions which had been submitted by members of the public before and during the meeting. Other questions not related to the agenda had been submitted in advance of the meeting and an action was taken to answer all remaining questions in writing to the people who raised them.

Action 82: Send written responses to observers whose questions were not answered during the April Board Meeting ***June Raine***

ANY OTHER BUSINESS

11.1 The Chair noted that this was Jon Fundrey's last Board meeting as Chief Operating Officer of the MHRA; the Board thanked Mr Fundrey for all his work as COO over the last 5 years as he leaves for a new role in the Civil Service.

ACTIONS FROM MHRA BOARD MEETING IN PUBLIC – 19 April 2022

The actions highlighted in red are due this month

Action Number	Action	Owner	Date	Status
Carried Forward from previous meetings				
29	16/03/21: Present an Agency Science Strategy to the Board.	Marc Bailey	~~21/09/21~~ ~~16/11/21~~ ~~15/03/22~~ ~~17/05/22~~ 15/11/22	
43	15/06/21: A revised assurance and governance framework for the new MHRA organisation should be presented to the Board.	Carly McGurry	~~15/02/22~~ ~~17/05/22~~ 20/09/22	
46	15/06/21: The Board's comments on the future development &branding of ILAP, including its potential use for medical devices, should be considered so that a definitive proposal can be presented to the Board for approval. 16/11/21: Consider if ILAP should be rebranded as an "Innovative Therapy Pathway" and conduct a pilot with a medical device through this innovative regulatory route.	Laura Squire	~~19/10/21~~ ~~16/11/21~~ ~~19/04/22~~ ~~21/06/22~~ 19/07/22	
51	20/07/21: Review Balanced Scorecard metrics and targets to provide more focus on outcomes, greater links to the Delivery Plan and (especially on innovation) and assurance that resources are available to deliver priorities 21/09/21: Review the outcome measures in the Balanced Scorecard and the RAG Ratings in the quarterly Delivery Plan reports before considering if the targets are ambitious enough. 19/10/21: Continue to evolve the Balanced Scorecard metrics to include outcome measures. Update the data set for Clinical Trials in the balanced scorecard. 16/11/21: Broaden the measures to include the impact and quality of our scientific work rather than volumes. Seek input from our customers on what MHRA	Jo Passingham	~~19/10/21~~ ~~16/11/21~~ ~~18/01/22~~ ~~15/03/22~~ ~~21/06/22~~ 20/09/22	

	services they value for inclusion in the Balanced Scorecard. 18/01/22: A new approach for Board Reporting on operational performance, risk management and opportunity progression to be recommended to the Board.			
52	18/01/22: The Board requested a review of the cross-agency actions that have delivered a meaningful and positive difference to patient safety and risk management in the two years since the Cumberlege Review was published.	Alison Cave	~~19/07/22~~ 20/09/22	
54	20/07/21: Review the progress and impact of the short, medium and long term deliverables of the agreed Culture, Equality, Diversity and Inclusion plans	June Raine	~~18/01/22~~ ~~15/02/22~~ ~~17/05/22~~ 20/09/22	
58	21/09/21: Update MHRA/DHSC Framework Agreement to coincide with the change in Trading Fund status.	Carly McGurry	~~31/03/22~~ ~~19/04/22~~ 21/06/22	On agenda
59	21/09/21: Board assurance committees to review their combined effectiveness and hold a board discussion on this topic.	Michael Whitehouse, Mercy Jeyasingham, & Mandy Calvert	~~15/03/22~~ 16/08/22	
61	19/10/21: Prioritise the national and international initiatives to accelerate the diversification of patient recruitment for clinical trials, exploring options to maintain diversification of representation (eg gender balance). Consider development of a public dashboard of metrics for trial recruitment. 18/01/22: Review feedback from public consultation on clinical trial regulations and make strategic recommendations on areas for development	Marc Bailey	~~19/04/22~~ 19/07/22	
62	19/10/21: Review the Corporate Risk Register to consider whether all strategic risks to Agency outcomes are accurately captured.	Carly McGurry	~~19/04/22~~ ~~17/11/22~~ 17/01/23	
64	16/11/21: Review opportunities for more partnership working with other regulators as part of the MHRA International Strategy	Glenn Wells	~~15/02/22~~ ~~19/04/22~~ 20/09/22	

65	16/11/21: PSEC to seek assurance on how safety risks are considered by the MHRA in those situations where patients are willing to accept more risk than healthcare professionals.	Mercy Jeyasingham	19/04/22	Completed
70	18/01/22: Develop and present a Data Strategy to the Board	Alison Cave & Claire Harrison	~~17/05/22~~ ~~18/10/22~~ 15/11/22	
71	18/01/22: Using the input from the public consultation and Board discussion, develop and publish a new regulatory framework for Artificial Intelligence as a Medical Device	Laura Squire	~~21/06/22~~ 20/09/22	
73	15/02/22: Develop a Green Regulatory Strategy	Laura Squire & Glenn Wells	17/01/23	
75	15/02/22: Provide details of Agency's Reverse Mentoring Scheme to Board Directors	Vanessa Birchall-Scott	~~15/03/22~~ 21/06/22	Completed – applications and matching ongoing
76	15/02/22: Ensure that monthly financial income and expenditure reports versus budget are available for every cost centre manager in the agency	Jo Passingham	01/04/22	Completed – this will be provided manually for the first 3 months of the financial year, then the process will be automated
77	15/02/22: Send written responses to observers whose questions were not answered during February Board Meeting	June Raine	15/03/22	Completed
New Actions				
78	19/04/22: Consider whether complaints escalated to the Parliamentary Ombudsman should be reported to the Board	Rachel Bosworth	21/06/22	Verbal Update
79	19/04/22: Hold a discussion on the Yellow Card Biobank at an upcoming Board meeting	Alison Cave	21/03/23	
80	19/04/22: Implement the Budget as approved by the Board for 2022/23. Ensure the deficit is balanced by end of the year.	Jo Passingham	31/03/23	
81	19/04/22: Continue to progress the work on the evolving approach to patient and public engagement; implement changes to questions at Board	Rachel Bosworth	21/06/22	Changes to public questions at the Board have been implemented
82	19/04/22: Send written responses to observers whose questions were not answered during April Board Meeting	June Raine	21/06/22	Completed

Medicines & Healthcare products Regulatory Agency

BOARD MEETING HELD IN PUBLIC

21 June 2022

Title	How much of the MHRA Delivery Plan was delivered in the first year of 2021/22?
Board Sponsor	June Raine
Purpose of Paper	Assurance

How much of the MHRA Delivery Plan was delivered in the first year of 2021/22?

Executive summary

1. We are halfway through our ambitious two-year, transformative Delivery Plan 2021-23. A new, transformed Agency has been created, which places patients and the public at the centre of all its activities. The learnings of the pandemic regarding regulatory flexibilities have been incorporated into the plans for development of new services. Proposals for legislative reforms are in hand to strengthen patient safety and support access to healthcare products, taking full advantage of the opportunities of EU Exit. Responding to the recommendations of the Cumberlege Review has been a key priority.

2. In reviewing the status of the Delivery Plan, the Executive Committee has concluded that overall, a huge amount has been implemented and we are on track to achieve the Delivery Plan's ambitions. Workload pressures have evolved over the year and are still live, including in areas where licence applications have been higher than anticipated. This has impacted capacity for some longer-term strategic deliverables, especially in relation to the delivery of technology projects. Out of a total of 58 specific deliverables there are 15 which now have revised due dates. These deliverables will receive extra focus this year.

3. The Board is asked to note this report and provide comments on the assurance given.

Introduction

4. The Executive Team manages the agency's performance process and oversees the implementation of the Agency's two-year Delivery Plan 2021-23. Each quarter, the executive leads assigned to the items in the plan provide a Red, Amber, Green (RAG) rating based on their confidence in successful delivery and also an action plan if they are going off-track. This information is reviewed by the Executive Committee and actions are agreed to get the work back on track. An overview of this is sent to the Board for assurance.

5. As we move into the second and final year of the Delivery Plan, the Executive Team has reviewed the plan and carried out a refresh to ensure the deliverables are still relevant, aligned to focus areas and achievable for year two. The Executive Team has taken the opportunity to define new focus areas and add new deliverables, and there has been a one-off managed opportunity to amend the due dates of some deliverables in light of the evolving workload over the year and challenges arising in-year.

6. The evolving Agency workload over the year has resulted from higher than expected work volumes, including applications for the new Innovative Licensing and Access Pathway, and reports of suspected adverse reactions (Yellow Cards). A particular challenge in-year has been the longer than anticipated processes for managers overseeing the transfer of staff to new teams as part of the Agency's transformation, which was a direct consequence of the Agency's commitment to following correct employment procedures which are fair to all staff.

7. This paper summarises progress to date, the plans for the second year and the status of performance as at Q4. Table 1 shows off-track deliverables and their agreed handling plans; and Table 2 shows the RAG rating for each item in the Delivery Plan.

Discussion

8. The majority of the deliverables due in the first year have been delivered. Importantly, we published and are delivering our **Patient Involvement Strategy** to ensure a more systematic approach to listening to and meaningfully involving patients. We have successfully delivered a new **One Agency** organisational structure, becoming a more simplified, joined-up and accessible organisation, which delivers for patients and the public. This helped to achieve financial sustainability and a **balanced financial budget** for 2022/23, together with a positive outcome of the Agency's proposals for funding through the Government's Comprehensive Spending Review.

9. In the first year after EU Exit we have made substantial progress in delivering **new access pathways**, in particular the Innovative Licensing and Access Pathway, which aims to introduce an end-to-end pathway for innovative new medicines by working in partnership with Health Technology Assessment bodies. We have also published proposals for legislative reform across a range of areas, notably in relation to **clinical trials** and **medical devices** where there is a huge opportunity for risk-proportionate regulation to facilitate access to new technologies such as software as a medical device and artificial intelligence.

10. We have established our position as a **sovereign regulator** with productive **international partnerships**. This includes participating fully in the Project Orbis initiative for new cancer drugs led by the USA Food and Drug Administration (FDA) and the Access Consortium (ie medical product regulators from Australia, Canada, Singapore, Switzerland and the UK) to enable earlier access to new products for patients and new access routes for product developers. MHRA applications for full membership of the International Conference on Harmonisation (ICH) and the International Medical Device Regulators Forum (IMDRF) have both been successful.

11. Taking into account the continued delivery of core functions, and a significant contribution to the UK's **COVID-19 response**, the Executive Team identified 15 existing deliverables that needed revised due dates, and agreed a one-off, managed update with additional scrutiny in 2022/23. The causes of these delays, summarised below, have lessened but continue to impact performance. Moreover, the delayed work will create a knock-on demand, a risk which the Executive Team is aware of and will manage this year.

    - **Staffing impacts from organisational change**: some staffing impacts remain but we are past the peak of disruption with around 90% of vacant posts now filled; we are now entering an on-boarding period for new staff particularly those with specialist skills and new teams are becoming established.

- **High than predicted workload in key areas**: new activities and the impact of EU Exit has led to higher than anticipated workload in key areas such as the Innovative Licensing and Access Pathway, national licence applications, and reports of suspected adverse reactions.
- **Prioritisation of COVID-19 work**: this important work in response to the global pandemic continues and is still demanding in some areas but has now moved off the initial emergency footing.

12. Almost all objectives remain due within the Delivery Plan's lifetime with minor exceptions where elements of work are planned to roll over. To make reporting simpler, items that the Executive Team marked as "business as usual" and were continually rated as Green, have been removed from reporting and will be managed locally.

Performance summary and action plans for off track items

13. There were 19 items due in Q4. We successfully delivered nine, the most notable of which was launching a consultation with proposals to enhance the **UK's clinical trials legislation**; our input into the UK work to secure the **negotiated settlement with the EU;** and delivering **prototype synthetic data research project**. The full list is summarised in Table 2 along with the other items delivered during the first year of our two-year Delivery Plan.

14. Of the remaining 10 items that were due in Q4:
    - Three slipped becoming Red / Amber, these are the next phase of the work to **extend the valproate registry**, and the **transformation programme** work due by Q4 along with associated **HR support.** The handling for these is covered in Table 1.

    - Seven had their due dates revised during the year two review. These are late but have reported against their updated due date, with a note that an extension was permitted, and extra scrutiny is needed to avoid further delays.

15. The Executive Team has considered and is assured by the handling plans for the 11 items that have been marked as going off-track. Details are shown in Table 1, there are 3 new Reds; 3 new Ambers and 5 Ambers that have rolled over from Q3.

16. The 3 new Reds and their handling plans are highlighted below. Overall, the main theme is the impact of the need to update budgets and plans now that the Spending Review outcome is known and also some wider resource and recruitment dependencies (currently unresolved but with plans in hand).

    - **New digital self-service platform**: the original deliverable (a One Agency single door self-service platform) went Red following the need to update our budgets in light of the Spending Review outcome. Since then, a rapid assessment was undertaken and the alternative option is supported of a subset of regulatory focused self-service being provided by the new Regulatory Management System (RMS). The new deliverable will be: "fully scope what self-service functionality can be delivered via the RMS by end Q2 2022/23" and it is assessed as Green.

- **Extend valproate registry UK-wide**: the initial version of the annual risk acknowledgment form was successfully developed by end Q4 2021/22. The functionality of the existing registry is being maintained, as the data is important for assessing the impact of wider regulatory action, while advice on whether further risk minimisation measures are required is sought from the Commission on Human Medicines.

- **Enhanced devices transparency regime**: a cross-agency group is being set up to drive this work forward and align with the new safety system functionality of SafetyConnect. A clearly defined transparency regime will be incorporated into the agency's Data Strategy, due to be presented to the Board in November. Full implementation is also dependent on provisions in the new Medical Devices legislation in light of the extensive responses to consultation.

17. The number of off-track deliverables has fallen from 23 to 11 in Q3. This reflects progress in several areas, as well as updated deadlines agreed during the review. For example, all four Reds raised in Q3 have been resolved: we completed the work allocating Agency reserves; we have identified an alternative funding mechanism for CPRD's observational research infrastructure project; and a technology solution was found to enable the inspections pilot of visual technology capabilities bringing that item back to Green.

Forward look to Delivery Plan Year Two (2022/23)

18. The Executive Team is proposing to refresh the Delivery Plan to ensure deliverables are aligned to focus areas and are achievable. In particular, it is proposed that there will be a focus on:

- **Patient involvement**: key actions included from our published patient involvement strategy to give this priority greater specificity and prominence to achieve meaningful outcomes.

- **Equity in Healthcare**: to reflect important new opportunities such as strengthening regulation addressing healthcare disparities (e.g. embedding requirements in legislation or guidance and improving the representativeness of our own data).

- **Transformation**: updated deliverables to capture the work essential to completing the Agency transformation.

Recommendation

19. The Executive Team has reviewed the status of the Delivery Plan at the end of the first year, has noted the good progress made in delivering transformation and it is proposing to refresh the plan focusing on priority areas as we move into the second year. The handling plans for current off-track items have been robustly scrutinised and there will be extra scrutiny for items with revised due dates. Overall, substantial ground has been covered and we are on track to achieve the ambitions of the Delivery Plan by 2023.

20. Nevertheless, it should be noted that the impacts and risks associated with the pressures of recent quarters, and ongoing vacancies, are still pertinent and this will need careful monitoring in year two. The ability to undertake a more quantitative impact assessment of delivery is something we plan to work on for next year.

21. The Board is asked to note this report on how much of the Delivery Plan 2021-23 has been delivered in the first year and provide comments on the assurance given.

Dr June Raine
CEO

Table 1: Delivery Plan Issues and Handling as at Q4

This table shows each deliverable flagged as off-track during Q4 and current handling plans.

Deliverable	Q1	Q2	Q3	Q4
Deliver a new **digital self-service platform** in beta by Q3, 2022/23 and live in Q4, 2022/23 to improve the service patients and customers receive.	G	A	A	R
Given the need to prioritise digital investment following the Spending Review outcome, we cannot deliver this as originally planned. Instead, we are exploring a limited self-service that can be covered by the Regulatory Management System (RMS). This will be covered in the Technology Delivery Paper which is due to be discussed at the Executive Committee shortly and we propose to amend this deliverable to: "fully scope what self-service functionality can be delivered via the RMS by end Q2 2022/23."				
Make available a **valproate UK-wide digital annual risk acknowledgment form** alongside defining the extension of **registry** to UK-wide by end of Q4, 2021/22.	G	G	G	R
The initial version of the annual risk acknowledgment form was successfully developed by end Q4 2021/22. The functionality of the existing registry is being maintained, as the data is important for assessing the impact of wider regulatory action, while advice on whether further risk minimisation measures are required is sought from the Commission on Human Medicines.				
Agreed policy for a **significantly enhanced transparency regime** for device regulation by ~~Q4, 2021/22~~ Q3, 2022/23, with key elements being delivered over 2022/23, and 2023/24.	A	A	G	R
A cross-agency group is being set up to drive this work forward and align it with the SafetyConnect platform. A clearly defined transparency regime will be incorporated into the agency's Data Strategy, due to be presented to the Board in November. Full implementation is also dependent on provisions in the new medical devices legislation.				
Deliver an **enhanced clinical trials service** by Q4, 2022/23 (TD[3]).	G	G	G	A
This item is dependent on securing alternative funding. We have identified an opportunity with the Office for Life Sciences (OLS), but this is unconfirmed at this time. The project will take at least nine months from when we hear so it is still possible to deliver if we get funding by end Q1. We are doing what we can in the meantime and are following up with the OLS.				
Launch Yellow Card Biobank 3 year project by end 2022 to define a sustainable business model and investigate the role of genetics in the development of adverse drug and vaccine reactions.	G	G	G	A
The full scoping project is complete. Additional funding is being actively sought to progress the project, a potential source has been identified and when it is secured this will go back to Green.				
Expand pilot process providing a **single decision on research using both a medicine and device** to a wider cohort of applicants and develop a process for the combined review of a product by Q1, 2022/23.	G	G	G	A
There is a live pilot in place for Med Devices, the "CTA/CI" pilot. This provides a preliminary route, but it is labour intensive and currently only covers initial applications. We expanded our scope to include in vitro diagnostics too but devices staff departures have stalled this. Recruitment is underway and that will bring this back on track.				

Ambers from last quarter				
Establish a new **devices legislative framework** to support safe innovation and ongoing access to products: lay Statutory Instrument by ~~end Q1, 2022/23~~ revised date to be agreed.	A	A	R	A
Work ongoing on strategic direction and policy. Initial challenges given staffing issues and scale of consultation response. Following useful discussions with the Department, a submission has gone to ministers covering outcome of the consultation and next steps. Once this is approved, we should be able to bring this back to Green.				
Deliver a set of work packages to ensure that **AI as a medical device** is underpinned by robust evidence to enable safer innovation by Q4, 2022/23.	A	A	A	A
We are in the process of reviewing the Roadmap for this work to update our project plan and bring this deliverable back to Green; we will be in a position to update on this next quarter. It was amber given historical delays. Given dependencies on legislative change, shifting to deliver non-legislative elements as soon as possible. Multiple products already drafted. Roadmap with deliverables will be progressing to clearances in April. “Software as a medical device” and “AI as a medical device” sections of the government response also drafted. We have agreement to explore further deliverables with the U.S. Food and Drug Administration (FDA) and to partner with a public-private partnership with the FDA to produce technical deliverables that fit both jurisdictions.				
Deliver **Transformation**, including benefits realisation, and restructure implementation; operationalisation of the future operating model and re-definition and optimisation of prioritised core services by the end of Q2, 2022/23. [AND] Deliver HR **support to staff during restructuring** throughout Q1-Q4, 2021/22.	A	A	A	A
Transition to the new structure started in January 2022. With considerable staff vacancies across the agency, the Executive Committee agreed an expedited process to drive selection and ensure job security for staff at-risk. We aim to complete the internal HR selection processes for those matched/mapped by the 30 April. Operationalisation of future operating model progressing with support being provided to core functions and their Chief Officers and teams. Programme Business Case approval was given for Year 2 and 3. Benefits are being validated and realisation will be reported on a quarterly basis. There are regular integration sessions with TD3 to facilitate the delivery of key components of Technology-enabled projects. Service prioritisation activities are underway and “Tiger Teams” have been formed to lead work. Further redesign and activity will be implemented from April 2022 due to capacity constraints of key stakeholders. As the programme moves into the next stage, priority areas are being agreed.				
Implement organisational design, creating a new, **leaner organisational structure and balancing costs** by ~~Q3, 2022/23~~ Q4, 2023/24.	A	A	A	A
We await any final conditions for the approval of the programme business case as well as the outcome of the SR, which may potentially have implications for the financial forecast and the need to balance our costs by Q4, 2023/24. We are working to prioritise the programme scope. Next steps: rephasing of programme of activity being considered by TD3, which may result in changes to spend across the 3-year period; and forward Plans defined with Chiefs to develop the next tranche of targeted areas for service transformation.				

Table 2: Delivery Plan Overall RAG Summary as at Q4

This table shows the RAG status for every item based on the amends agreed in the year two review. Green text shows amends to existing items following progress and red text shows amends to due dates of existing deliverables.

#	Deliverable	Due date	Q1	Q2	Q3	Q4
ENABLE SCIENTIFIC INNOVATION – Marc Bailey ***Global biological standards, regulatory science, clinical trials and clinical investigations***						
1	Encourage a more innovative and pragmatic approach to clinical trials via an initiative to facilitate the uptake of novel trial designs and a comms effort to tackle the misperceptions that "traditional" clinical trials are always required for a licence by Q4, 2021/22.	Q4, 2021/22	G	G	G	B
2	Develop mechanism to pilot joint clinical trial approval and clinical trial and licensing scientific and compliance advice via Access Consortium ~~by Q4, 2021/22;~~ next step to agree deliverables with Access partners and run pilot (if interest available) by end Q2 2022/23	Q4, 2021/22	G	G	G	G
3	Publish new Regulatory Science Strategy, incorporating laboratory and standards sub-strategies, by end ~~Q4, 2021/22~~ Q1, 2022/23; and implemented from ~~Q1 2022/23~~ Q2, 2022/23.	Q1, 2022/23	G	G	A	G
4	Expand pilot process providing a single decision on research using both a medicine and device to a wider cohort of applicants and develop a process for the combined review of a product by Q1, 2022/23.	Q1, 2022/23	G	G	G	A
5	Consult on options for changing UK legislation to make conduct of trials generating real-world data easier, including options to encourage the inclusion of underserved populations and increasing diversity in clinical research by Q4, 2021/22; publish consultation response by end Q2, 2022/23 and lay Statutory Instrument by end Q3 2022/23. (Updated to reflect next milestone/s)	Q2, 2022/23	G	G	G	B
6	Integrate with the Health Research Authority and National Institute for Health and Care Research's Clinical Research Network to provide a fast track approval for defined clinical trials – support pilot to set up phase 1 oncology trials by end Q4, 2022/23	Q4, 2022/23	G	B	G	G
7	Risk-based approach to batch release: guidelines drafted by Q3, 2021/22 implement independent testing based on risk based strategy by Q4, 2022/23.	Q4, 2022/23	G	G	G	G

ACCELERATE HEALTHCARE ACCESS – Laura Squire & Glenn Wells (for items 8-15) *Innovative access and reliance procedures, new medical device regulations and risk-proportional processes for well-established products*						
8	Lay SIs for 1st tranche responses by end Q3, 2022/23 (updated with final laying date) and ensure Health and Care Bill Medicine Information System powers come into force by Q2, 2022/23	Q2 / Q3, 2022/23	A	G	A/G	G
9	Identify key policy areas for second tranche of legislative change and define timescales for laying SIs over 2022/23 and beyond by end Q1, 2022/23.	Q1, 2022/23	NA	NA	NA	G
10	Reduce regulatory burden by identifying which flexibilities introduced in response to COVID-19 are safe to embed by ~~Q3, 2021/22~~ Q1 2022/23.	Q1, 2022/23	G	G	A/G	G
11	~~Resolution of any live regulatory issues following EU transition by Q1, 2022/23.~~ Develop EU implementation programme and taskforce to enact proposals following EU negotiated outcome, and subsequent legislation to update EU Acquis; Programme established by end Q1, 2022/23. (Amended to reflect next steps).	Q1, 2022/23	A	A	G	B
12	Formulation of future of EU reliance procedures in line with broader international licencing assessment partnerships by end Q2, 2022/23. (Development of work following above).	Q2, 2022/23	NA	NA	NA	G
13	Consult on a national GB scheme to replace Falsified Medicines Directive safety features regulation by end ~~Q4, 2021/22~~ Q3, 2022/23; lay Statutory Instrument as per Departmental timescales; and agree position on Falsified Medicines Directive for Northern Ireland post 3-year EU derogation by end Q4, 2022/23 (Updated to align with latest Departmental position)	Q3, 2022/23	G	G	G	G
14	Deliver the GB Medicines Verification System, to replace the EU system and enable medicines to be tracked through the supply chain; launch consultation by Q3, 2022/23; lay Statutory Instrument as per Departmental timescales. (Updated to align with latest Departmental position)	Q3, 2022/23	G	G	G	G
15	Roll out of automated inspection reports by Q4, 2021/22: Good Manufacturing / Distribution Practice and Good Laboratory Practice	Q4, 2021/22	A	A	B	B
	Good Clinical Practice and Good Pharmacovigilance Practice				G	B
16	Embed visual technology capabilities as a standard part of inspections by Q3, 2022/23.	Q3, 2022/23	G	G	R	G
17	Deliver a world-leading approach to inspections with assurance that products are developed and manufactured to the highest standards through the implementation of a new compliance strategy ~~throughout 2021/22 and 2022/23~~, including the piloting of consultants as 'compliance monitors' in remediation cases, by end Q3, 2022/23. (Updated to include a deadline and work on compliance monitors removed as separate item and added to this item and date amended from Q2 to Q3)	Q3, 2022/23	A	A	A	G

18	Ensure integrated UK regulatory pathways for products that combine medicinal products and devices; consultation ~~Q3, 2022/23~~ Q4, 2022/23	Q4, 2022/23	G	G	G	G
19	Deliver a set of work packages to ensure that AI as a medical device is underpinned by robust evidence to enable safer innovation by Q4, 2022/23.	Q4, 2022/23	A	A	A	A
20	Establish a new devices legislative framework to support safe innovation and ongoing access to products: lay Statutory Instrument by revised date to be agreed.	Revised date to be agreed	A	A	R	A
21	Further develop a financially sustainable Innovative Licensing and Access Pathway framework by creating a world-class first port of call for medical product development and access (medicines, medical devices and combination products); implement a strategic plan for the next phase of the pathway's development in collaboration with partners, industry and patients by end Q3, 2022/23; before launching the enhanced operational model in early 2023.	Q3, 2022/23	G	G	G	G
STRENGTHEN PATIENT SAFETY – Alison Cave ***Pro-active surveillance and enforcement, real world data management, optimal risk communication and patient involvement***						
22	Make available a valproate UK-wide digital annual risk acknowledgment form alongside defining the extension of valproate registry to UK-wide by end of Q4, 2021/22.	Q4, 2021/22	G	G	G	R
23	Agreed policy for a significantly enhanced transparency regime for device regulation by ~~Q4, 2021/22~~ Q3, 2022/23, with key elements delivered over 2022/23, and 2023/24.	Q3, 2022/23	A	A	G	R
24	~~Deliver NHSX funded synthetic data research project by Q4, 2021/22 and launch prototype synthetic data generation service by Q2, 2022/23~~ Deliver expanded scope of NHSX funded synthetic data research project and launch the synthetic data service by Q4 2022/23. (Deadline amended as scope of work expanded following additional funding from NHSX)	Q4, 2022/23	G	G	G	B
25	~~*Improve model of DEAC and its EAG by Q3, 2021/22 (plan to be agreed by Q3), to ensure greater involvement of independent, scientific, technical, lay and clinical experts in regulatory decision making.*~~ Improve the model of the Devices Expert Advisory Committee to ensure greater involvement of independent, scientific, technical, lay and clinical experts in regulatory decision making: launch consultation by end Q3 2022/23; and establish statutory committee by July 2023. (Updated to reflect next milestone/s)	Q3, 2022/23	A	G	B	G
26	Review of teratogen use during pregnancy, consideration of the strategies of other regulators by ~~Q3, 2021/22~~ Q1, 2022/23; with independent patient / stakeholder input and expert advice in ~~Q4, 2021/22~~ Q2, 2022/23; and, if required, updated action and guidance by Q2, 2022/23.	Q1, 2022/23	G	G	A/G	G

27	Deliver Safety Connect to ensure enhanced signal detection process by ~~Q4, 2021/22~~ Q3, 2022/23; and service enhancement and international opportunities to defined in ~~Q4, 2021/22~~ Q2, 2022/23; and delivered in 2022/23.	Q3, 2022/23	G	G	G	G
28	Upgrade our observational research infrastructure to enable timely and secure delivery of research data services: map out requirements and commence implementation of new systems by Q2, 2022/23.	Q2, 2022/23	G	A/R	R	G
29	~~*Deliver an options appraisal for our project to investigate the role of genetics in the development of adverse drug and vaccine reactions by Q3, 2021/22.*~~ Launch Yellow Card Biobank 3 year project by end 2022 to define a sustainable business model and investigate the role of genetics in the development of adverse drug/vaccine reactions. (Updated to reflect next steps)	Q3, 2022/23	G	G	B	A
DYNAMIC ORGANISATION – Davinder Virdi/Vanessa Birchall-Scott ***Completing our Transformation and People Programmes***						
30	~~Deliver accompanying Transformation and organisational redesign (staffing, governance, structures, processes) by Q4, 2021/22 and post implementation support including benefits realisation from April 2022 onwards.~~ Deliver Transformation including plan for benefits realisation, and restructure implementation (completion of the selection process and recruitment activity); operationalisation of the future operating model (staffing, governance, and structures) and re-definition and optimisation of prioritised core services by the end of Q2, 2022/23.	Q2, 2022/23	A	A	A	A
31	Review and revise plan and share with Department by Q1, 2022/23 as part of annual business planning.	Q1, 2022/23	G	G	G	G
32	Launch staff leadership action plan by Q2, 2021/22.	Q2, 2021/22	G	G	A	B
33	Deliver HR support and guidance to staff during organisational restructuring throughout Q1-Q4, 2021/22.	Q4, 2021/22	G	A	A	A
34	Develop an organisational culture action plan by Q1, 2021/22; deliver associated actions in line with the Q1-Q4 deadlines within the plan, including refreshing the plan in Q1, 2022/23	Q1, 2022/23	B	G	G	G
35	Identify future workforce / talent needs and ensure we embed workforce planning by Q2, 2021/22; having reviewed workforce in Q1, 2022/23 and identified follow-up actions.	Q1, 2022/23	G	B	G	G
36	Publish People Strategy that aligns with the agency vision, values and Delivery Plan by end Q2, 2022/23..	Q2, 2022/23	NA	NA	NA	G
37	Deliver Employee Value Proposition to attract and train talent, and build our reputation as an employer of choice by end Q3, 2023/23.	Q3, 2023/23	NA	NA	NA	G

COLLABORATIVE PARTNERSHIPS – Glenn Wells ***Leverage international and UK healthcare system partnerships to drive better outcomes***						
38	Finalise International Strategy by ~~Q1, 2021/22~~ end Q2, 2022/23.	Q2, 2022/23	B	B	A/G	G
39	Full assessment of the linkages needed with the World Health Organisation, including in the context of biological and control standards by ~~Q2 2021/23~~ Q2, 2022/23.	Q2, 2022/23	G	A	A/G	G
40	Map key partnerships for delivery and refresh relationships ~~with detailed work programmes from Q2 and in place by Q4, 2021/22~~; initial paper to Board by end Q1, 2022/23.	Q1, 2022/23	G	A	A/G	G
41	Encourage more effective collaboration between relevant partners and stakeholders to support each new operational group by developing standard operating practices and scope supportive technology infrastructure by end Q4, 2022/23. (addition to item above)	Q4, 2022/23	NA	NA	NA	G
COLLABORATIVE PARTNERSHIPS – Rachel Bosworth/June Raine ***Build public and stakeholder trust through a programme of proactive communications***						
42	Deliver the actions in our Public Engagement and Involvement Strategy, (as per agreed actions and deadlines – to follow)	As above	G	B	A	G
43	Enhance Customer Service Centre to support effective engagement with patients and customers, enabling them to access the info they need when they need it from Q4, 2021/22.	Q4, 2021/22	G	G	G	B
44	Complete main elements of agency rebranding to ensure consistency and raise our profile by end Q2, 2022/23.	Q2, 2022/23	NA	NA	NA	G
45	Launch consultation on proposals for engaging with healthcare professionals by end Q2, 2022/23.	Q2, 2022/23	NA	NA	NA	G
46	Develop Risk Communication Strategy to ensure more coordinated, pro-active safety comms by end Q4 2023/23.	Q4, 2023/23	NA	NA	NA	G
FINANCIAL SUSTAINABILITY – Jo Passingham ***Establish a new business model that increases income, reduces costs and improves productivity***						
47	Use available cash reserves to fund necessary systems investments, operational deficits and restructuring costs until the end of our Trading Fund status at the end of 2021/22.	Q4, 2021/22	G	R	R	B
48	Develop, consult on (Q2,2022/23) and implement a new fee structure from Q1 2023/2024	Q2, 2022/23	A	G	G	G
49	Reduce corporate costs by 15% by the end of 2022/23.	Q4, 2022/23	G	G	G	G
50	Reduce non-pay costs of £60m by £6m per year through procurement and contract management by the end of 2022/23.	Q4, 2022/23	G	G	G	G
51	Implement organisational design, creating a new, leaner organisational structure and balancing costs by ~~Q3, 2022/23~~ Q4, 2023/24.	Q4, 2023/24	A	A	A	A

FINANCIAL SUSTAINABILITY – Claire Harrison *Deliver optimised IT infrastructure to improve service & reduce costs with fewer digital technologies*						
52	Finalise plan to overhaul costly legacy systems by Q1 2022/23; start to deliver improved service and savings from Q4, 2021/22.	Q1, 2022/23	G	R	A	G
53	Deliver Data Strategy, including a data sharing strategy, underpinned with robust security standards and privacy by design by ~~Q3, 2021/22~~ end Q3, 2022/23.	Q1, 2022/23	G	G	A/G	G
54	Improve our ability to exchange data with partners by adopting international standards (including "Identification of Medicinal Products" regulations); define adoption approach by Q2, 2022/23; new system full implementation by Q1, 2023/24.	Q2, 2022/23	G	G	G	G
55	Deliver a new digital self-service platform in beta by Q3, 2022/23 and live in Q4, 2022/23 to improve the service patients and customers receive. [to be changed to "fully scope what self-service functionality can be delivered via the RMS by end Q2 2022/23"]	Q3, 2022/23	G	A	A	R
56	Deliver an enhanced clinical trials service by Q4, 2022/23.	Q4, 2022/23	G	G	G	A
57	Support revised devices regulations, deliver the digital self-service, automation and data platforms required by Q1, 2023/24	Q1, 2023/24	G	G	G	G
58	Deliver regulatory management core system by Q1, 2023/24.	Q1, 2023/24	G	R	A	G

Medicines & Healthcare products Regulatory Agency

BOARD MEETING HELD IN PUBLIC

21 June 2022

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

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

1. Executive Summary

1.1 The Audit and Risk Assurance Committee (ARAC) met on 24 May. We received an update from Finance and External Audit on progress in finalising and auditing the MHRA's financial statements and Annual Report for 2021-22. We considered the latest draft of the Agency's annual governance statement. Finally, we reviewed Internal Audit's most recent report on corporate governance.

1.2 We meet again on 20 June when we will review the audited Financial Statements and receive the National Audit Office (NAO) report as the Agency's statutory external auditor. ARAC will provide an oral update to the Board at its meeting on 21 June. This timetable should enable the Board to advise the Accounting Officer that she can sign the MHRA's Financial Statements prior to them being laid in Parliament before the Summer Recess. We have agreed contingency arrangements should there be any outstanding issues requiring further work after 20 June.

2. Progress with the MHRA's Financial Statements for 2021-22.

2.1 Finance presented a comprehensive paper on the key accounting and audit issues which require resolution before external audit can certify the MHRA's Financial Statements. These include confirmation of the treatment and disclosure of certain types of income; the impact of the end of Trading Fund status; bad debt write-off; and the treatment of redundancies in the accounts. We were assured by Finance and the NAO and KPMG that at this point in time the list of issues was as complete as it could be. Work is sufficiently advanced to address all of them to provide the evidence which External Audit require. Two issues need Treasury authority: a 2020 severance payment and a VAT payment related to Clinical Practice Research Datalink (CPRD) income. The NAO is supporting the Agency in securing Treasury approval.

2.2 The timetable to complete the audit remains tight but the Committee was assured that good progress is being made by both the Agency and External Audit.

3. Progress with the Governance Statement.

3.1 The Treasury's Financial Reporting Manual (FREM) requires that all public entities publish with their Annual Report an Accountability Report which sets out how key accountability requirements to Parliament have been met. A key section of the Accountability Report is the Governance Statement which should summarise how the entity identifies and manages risk; its key internal controls; and how ongoing assurance is secured that these continue to be effective. Auditors are required to review the Accountability report for consistency with other information in the financial statements.

3.2 The Agency's Governance Office is responsible for preparation of the Agency's Annual Report including the Governance Statement. We were pleased to receive a draft of the Statement and appreciated the considerable work that had gone into preparing this. We made a number of suggestions as to how the draft can be further enhanced. These included: streamlining and removing duplication; setting out the root cause of an issue and the action being taken by the Agency to remedy it; and ensuring that the presentation of risks and their management was sufficiently strategic. We also discussed "tone" and the importance that the Governance Statement conveyed authority - the last 12 months had been challenging, some control weaknesses had become apparent, the Agency is completely transparent about these but has clear action in hand or planned to address them in a demanding but realistic timeframe.

4. Internal Audit

4.1 Internal Audit has two final reports to complete as part of its 2021-22 programme. We received the first of these on the Agency's new governance arrangements. The second on the Innovative Licensing and Access Pathway (ILAP) is well advanced and will review the report at our June meeting.

4.2 Internal Audit awarded a moderate assurance opinion as a result of its review of the Agency's new governance structure. This is a positive result. Internal Audit acknowledged that the Agency's new structures are fundamentally sound but need more time to embed. Internal Audit had some concern that delegated authority setting out the decisions which can be taken within the new structure were unclear or needed to be defined. The Agency accepts this and intends to take action.

4.3 ARAC took assurance that the governance framework was sound but discussed the underlying culture which needs to be sustained if governance is to be consistently effective. The Committee noted a tendency for decisions to be routinely escalated to a more senior level and this was reinforced by Internal Audit's finding that delegated authorities needed greater clarity and understanding. We support the Accounting Officer's assessment that part of the wider cultural change which the Agency is seeking to embed is staff being empowered and taking responsibility within an appropriate governance framework. We agreed that achieving this ambition is something which the Organisation Design and Remuneration Committee (ODRC) and Board may want to monitor.

4.4 We reviewed progress in implementing Internal Audit's recommendations. We were pleased to note that very few recommendations are outstanding. The Committee drew attention to a significant proportion of recommendations becoming due for implementation over the next six months. It will be important that the Agency does not lose focus in ensuring that these are implemented as planned and that they mitigate the risk which the recommendation was originally intended to address. Transformation or external factors may mean that a recommendation is no longer relevant or is potentially sub-optimal. Should this be the case the Agency should agree with Internal Audit whether the recommendation remains relevant or needs to be changed. This should be reflected in the report to ARAC.

5. Reporting to the Department of Health and Social Care (DHSC)

5.1 As the MHRA is no longer a Trading Fund, it now has to report its financial performance to DHSC more regularly. The first formal reporting return is at the end of June covering the first quarter of 2022-23. Finance assured us that that they would meet this deadline and provide the financial information required by the Department.

Michael Whitehouse
Chair of ARAC
May 2022

Medicines & Healthcare products Regulatory Agency

BOARD MEETING HELD IN PUBLIC

21 June 2022

Title	What were the financial results of the MHRA in 2021/22?
Board Sponsor	Joann Passingham
Purpose of Paper	Assurance

What were the financial results of the MHRA in 2021/22?

1. Executive Summary

1.1 The paper sets out the MHRA financial performance in 2021/22 as set out in the draft Annual report and Accounts [unaudited]. The Board is asked to note the Agency's financial performance and outturn for the last financial year and consider the implications for the current financial year.

2. Introduction

2.1 The paper presents the Agency's financial outturn for the 2021/22 financial year as set out in the draft Annual Report and Accounts. As the audit fieldwork is still ongoing these figures are currently based on the latest draft of the financial statements.

3. Financial Review 2021/22 (unaudited)

3.1 The Agency's financial performance in 2021/22 reflects the continued change in the Agency's sources of funding and revenue after the UK's exit from the European Union. This financial year the agency's performance has also continued to be impacted by the pandemic.

3.2 As a Trading fund the Agency is required by a HM Treasury Minute to achieve a return averaged over the five-year period from 1 April 2018 to 31 March 2023, of at least 3.5% in the form of an operating surplus on ordinary activities before interest and dividends expressed as a percentage of average capital employed. Capital employed consists of the Agency's capital and reserves. The Agency change is status from 1 April 2022 will mean that this dividend will no longer be payable in the future.

3.3 The Agency is funded mostly by income from fees for both statutory and non-statutory sales of products and services. Trading income from external customers arising from fee charging statutory activities and commercial activities in 2021/22 was £150.3m which was £3.8m higher than in 2020/21. The increase in revenue was due to an increase in volume of service fees as more licenses were needed following the UK exit from the EU and an increase in our sale of pharmaceutical standards. Income from our devices work was also higher due to a change in legislation that increased the products requiring registration.

3.4 DHSC provides funding for a range of MHRA services that are either not commercial or for which we do not have the legal basis to charge for. This year funding for activities from DHSC was £30.0million, £13.4million lower than last year due to the phasing out of the EU exit support and the end of additional pension funding paid over the last two years.

3.5 Staff costs decreased by £1.5m (1.62%) reflecting mainly a 7.8% decrease in the average number of employees, both permanently and temporarily employed.

3.6 The resulting 2021/22 operating deficit before interest and dividends was £9.0m compared to £0.03m in 2020/21. The main reason for this deficit was the investment made in transforming the agency following the UK exit from the EU. We spent £11.8million on transformation during the year. This includes £4.7million on redundancies through a voluntary exit and a voluntary redundancy scheme, with the balance predominantly being external consultancy costs. The cost of the transformation was paid for out of the trading fund reserves. The completion of the transformation going forwards, including improvements in our technology and processes is being supported by DHSC.

3.7 After dividends payable of £14.9m a net deficit of £23.9m was transferred to reserves.

3.8 2021/22 has seen a net cash outflow from operating activities of £8.9m compared to an outflow of £2.9m in 2020/21. The current year operating cash outflow was driven by the operating deficit of £9.0m adjusted for non-cash items (add back depreciation of £11.4m; less DHSC non-cash funding of £12.4m) along with a £1.2m cash inflow from a decrease in working capital.

3.9 Cash for purchases of tangible and intangible assets was a further outflow of £15.5m and there was a net cash outflow of £4.2m from financing activities, mainly the payment to DHSC of a cash dividend of £2.8m and the repayment of the loan of £1.3m. As a result, cash and cash equivalents at the end of 2021/22 financial year were £28.6m lower than at the end of 2020/21.

4. Recommendation

4.1 The Board is asked to consider the financial performance of the Agency and the implications for the current financial year, in particular the path towards achieving financial sustainability.

4.2 The Board is asked to take note of the financial outturn for the 2021/22 financial year, subject to final audit sign-off.

Joann Passingham
Interim Chief Financial Officer
21 June 2022

EXTRACT FROM DRAFT 2021/22 ANNUAL REPORT AND ACCOUNTS

Statement of comprehensive income for the year ended 31 March 2022

	NOTE	2021/22 £000	2021/22 £000	2020/21 £000	2020/21 £000
Income					
Trading income	3.1		**150,329**		146,546
Other income	3.2		**12,446**		12,425
Total income			**162,775**		158,971
Expenditure					
Staff costs	5	**(90,948)**		(92,439)	
Operating costs	6	**(80,846)**		(66,506)	
Total expenditure			**(171,794)**		(158,945)
Operating (deficit)/surplus			**(9,019)**		26
Finance income			**35**		6
Finance costs			**(47)**		(47)
Deficit for the financial year			**(9,031)**		(15)
Other comprehensive income					
Realised loss on inventories			**(85)**		(188)
Net gain/(loss) on revaluation of property, plant and equipment*	7		**6,054**		(3,334)
Total comprehensive loss income for the year			**(3,062)**		(3,537)

*All gains and losses arise from continuing operations.

Statement of financial position as at 31 March 2022

	NOTE	31 March 2022		Restated 31 March 2021	
		£000	**£000**	£000	£000
Non-current assets					
Property, plant and equipment	7	**135,404**		128,464	
Intangible assets	8	**16,402**		13,389	
Inventories	10	**9,473**		9,069	
Trade and other receivables	11	**6,330**		7,291	
Total non-current assets			**167,609**		158,213
Current assets					
Inventories	10	**661**		494	
Trade and other receivables	11	**48,577**		43,942	
Cash and cash equivalents	12	**51,047**		79,601	
Total current assets			**100,285**		124,037
Total assets			**267,894**		282,250
Current liabilities					
Trade and other payables	13	**(45,574)**		(44,729)	
Other liabilities	14	**(30,417)**		(24,860)	
Provisions	15	**-**		(1,781)	
Total current liabilities			**(75,991)**		(71,370)
Total assets less current liabilities			**191,903**		210,880
Non-current liabilities					
Other liabilities	14	**(4,904)**		(4,602)	
Provisions	15	**(1,998)**		(1,998)	
Borrowings		**-**		(1,328)	
Total non-current liabilities			**(6,902)**		(7,928)
Assets less liabilities			**185,001**		202,952
Taxpayers equity					
Public dividend capital			**1,329**		1,329
Reserves					
Revaluation reserve			**117,602**		111,633
Income and expenditure reserve			**954**		954
General fund			**65,116**		89,036
Total equity			**185,001**		202,952

Statement of cash flows for the year ended 31 March 2022

	NOTE	2021/22 £000	2021/22 £000	2020/21 £000	2020/21 £000
Cash flows from Operating activities					
Operating (deficit)/surplus		**(9,019)**		26	
Depreciation and amortisation	7/8	**11,425**		10,338	
Loss on disposal of assets	7/8	**182**		40	
Impairment of property, plant and intangible assets	7/8	**21**		462	
Realised loss on inventories	10	**(85)**		(188)	
(Increase) in inventories	10	**(571)**		(3,725)	
(Increase) in trade and other receivables	11	**(3,674)**		(9,394)	
(Decrease) in trade and other payables	13	**(11,217)**		(3,342)	
Increase in other liabilities	14	**5,859**		762	
(Decrease)/increase in provisions	15	**(1,781)**		2,068	
Net cash (outflow) from operating activities			**(8,860)**		(2,953)
Cash flows from investing activities					
Purchase of property, plant & equipment	7	**(8,588)**		(2,214)	
Purchase of intangible assets	8	**(6,939)**		(1,789)	
Net cash (outflow) from investing activities			**(15,527)**		(4,003)
Cash flows from financing activities					
Interest received		**35**		6	
Interest paid		**(47)**		(47)	
Repayment of borrowings		**(1,328)**		-	
Dividend paid		**(2,827)**		(2,687)	
Net cash (outflow) from financing			**(4,167)**		(2,728)
Net (decrease) in cash and cash equivalents in the financial year	12		**(28,554)**		(9,684)
Cash and cash equivalents at the beginning of the financial year	12		**79,601**		89,285
Cash and cash equivalents at the end of the financial year	12		**51,047**		79,601

Statement of changes in taxpayer's equity for the year ended 31 March 2022

	PDC	General Fund	Reval. reserve	I & E reserve	Total
	£000	£000	£000	£000	£000
Balance at 31 March 2020	**1,329**	**104,303**	**115,155**	**954**	**221,741**
Changes in taxpayer's equity for 2020/21				`	
(Deficit) for the year	-	(15)	-	-	(15)
Other changes					
Net loss on revaluation of property, plant and equipment	-	-	(3,334)	-	(3,334)
Realised loss on inventories - biological standards	-	-	(188)	-	(188)
Dividend payable	-	(15,252)	-	-	(15,252)
Sub total	-	(15,252)	(3,522)	-	(18,774)
Balance at 31 March 2021	**1,329**	**89,036**	**111,633**	**954**	**202,952**
Changes in taxpayer's equity for 2021/22				`	
Deficit for the year	-	(9,031)	-	-	(9,031)
Other changes					
Net gain on revaluation of property, plant and equipment	-	-	6,054	-	6,054
Realised loss on inventories - biological standards	-	-	(85)	-	(85)
Dividend payable	-	(14,889)	-	-	(14,889)
Sub total	-	(14,889)	5,969	-	(8,920)
Balance at 31 March 2022	**1,329**	**65,116**	**117,602**	**954**	**185,001**

Medicines & Healthcare products Regulatory Agency

BOARD MEETING HELD IN PUBLIC

21 June 2022

Title	How will the performance and governance of the MHRA be reflected in the 2021/22 Annual Report?
Board Sponsor	Carly McGurry
Purpose of Paper	Approval

How will the performance and governance of the MHRA be reflected in the 2021/22 Annual Report?

1. Executive Summary

1.1 The MHRA 2021-2022 Annual Report and Accounts has been prepared by the Governance Office, working with Chief Officers and key stakeholders internally, and in collaboration with Finance and Communications colleagues. The report must be submitted by 14 July 2022 so it can be laid prior to Parliament rising on 21 July 2022.

1.2 The draft report has been reviewed by the Sponsorship Team at the Department of Health and Social Care (DHSC), Audit, Risk and Assurance Committee (ARAC) and by National Audit Office (NAO) auditors, who have provided guidance in the finalising of the narrative, key messaging and structure.

1.3 The 2021-2022 Annual Report and Accounts will be presented as a final version to the ARAC on 20 June 2022 prior to the Board meeting on 21 June. ARAC will review the report, seek assurance from the Agency and its auditors and, if appropriate, provide a recommendation for the Chief Executive, as Accounting Officer, to sign off the report.

1.4 The Accounting Officer will additionally receive assurance from Chief Officers, through signed Annual Assurance Statements, that significant areas of internal controls have been followed for their areas during the financial year.

1.5 The Board is asked to agree that the annual report and accounts can be signed off subject to a review and favourable report by Audit Risk and Assurance Committee.

2. Background

2.1 There is a mandatory requirement on government bodies to produce and publish a report and accounts each year and lay them before Parliament. The Annual Report and Accounts enables Parliament to hold the Government and its agencies to account as well as enabling the public to understand and consider the value for money offered by public spending.

2.2 The Government Financial Reporting Manual (FReM), published by HM Treasury, sets out mandatory guidance for preparing the Annual Report and Accounts to ensure that it conforms to accounting practises and presents a true and fair view of the organisation. FReM outlines the required format and content that all reports must comply with and recommends additional best practise.

2.3 Creation of the MHRA Annual Report and Accounts for 2021/22 financial year is being coordinated by the Governance Office for the first time but has been managed with significant collaboration between the Governance Office, Finance team and Communications team.

2.4 The report sets out key highlights of our performance against the Delivery Plan over the course of its first year, along with supporting performance metrics. It also covers the progress that the Agency has made in its transformation programme over the course of the year. The report complies with the requirements of FReM in providing an Accountability Report, made up of a Corporate Governance Report, a Remuneration and Staff Report and a Parliamentary Accountability and Audit report. These set out the various controls in place across the Agency across a range of issues to provide assurance to Parliament that we are operating in accordance with the relevant requirements. Finally, the document includes the required financial statements.

2.5 The Financial Statements, Accounts and Governance Statement section of the report have been subject to external audit by KPMG and NAO. The draft report has also been shared with our sponsor team at DHSC over the course of its development, and an earlier draft presented to ARAC at its May meeting. The final draft of the financial statements will be presented to ARAC at its meeting on 20 June and have been included in the agenda of this Board Meeting.

3. Recommendation

3.1 The Board is asked to consider if it is content to approve the Annual Report and Accounts, subject to the detailed review and recommendation from ARAC at its meeting on 20 June, so that the Chief Executive, as Accounting Officer, can sign off the document.

Carly McGurry
June 2022

Medicines & Healthcare products Regulatory Agency

BOARD MEETING HELD IN PUBLIC

21 June 2022

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

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

'TOP 10' HEADLINES

- Progress with One Agency transformation discussed at All Staff meeting on 31 May and with over 90% posts now filled, the new structure is operational from 1 June.
- Services Review underway and prioritising risk-proportionate approach to established medicines, facilitating access to innovative products, and compliance strategy.
- A hybrid working policy, in line with Department of Health and Social Care, has been communicated to staff along with focus on maximising collaboration opportunities.
- Patient involvement in regulatory procedures is an ongoing priority with participation in Commission on Human Medicines meetings on valproate risk minimisation.
- Major enhancements facilitating patient updates deployed to the Yellow Card platform through the SafetyConnect programme to deliver on commitments in the Cumberlege Review.
- Membership of International Conference on Harmonisation approved, supporting MHRA role in achieving international convergence of pharmaceutical requirements.
- First product granted an Innovation Passport under the Innovative Licensing and Access Pathway (belzutifan) approved via US FDA Orbis initiative for cancer drugs.
- Educational workshops held to inform industry and pharmacists on meeting regulatory requirements to support access to hormone replacement therapy.
- Work continues with companies to support access to suitable vaccines and treatments for monkeypox in the UK.

1. SCIENTIFIC RESEARCH AND INNOVATION

Update on establishing Yellow Card Biobank

1.1 Work on Yellow Card Biobank scoping is progressing, priority being to secure funding to enable a move into the set-up phase of the project. The team has undertaken stakeholder engagement with genomics organisations, researcher units and academics to look at collaboration opportunities and to better understand use cases and user requirements for a Yellow Card Biobank to finalise the strategy.

Update on the CPRD SPRINT service

1.2 Launched in 2020, the CPRD SPRINT (Speedy Patient Recruitment INto Trials) service is tailored to support commercial organisations rapidly recruit high quality patients living with chronic conditions in the community, into phase 2 and 3 trials. Generating a tight funnel of high-quality potentially eligible patients through near real-time centralised searches of UK-wide electronic health records against protocol criteria, selected patients can be geolocated around clinical sites in any setting across the UK. Currently there are two contracted CPRD SPRINT studies under way.

Global polio eradication

1.3 Our scientists participating in the scientific consortium working on how the novel oral polio vaccine, serotype 2 (nOPV2) can be utilised as a safer treatment than earlier vaccines have featured in a video interview produced by the Gates foundation. Video link: https://polioeradication.org/news-post/coffee-with-polio-experts-dr-ananda-bandyopadhyay-bill-melinda-gates-foundation/.

Coalition for Epidemic Preparedness Innovations on SARS-COV-2

1.4 The Coalition for Epidemic Preparedness Innovations (CEPI) has extended the existing contract whereby MHRA is a member of the Centralised Laboratory Network to measure the immune responses elicited by vaccine candidates against SARS-COV-2. The expanded network will include testing of vaccine candidates for CEPI's priority pathogens and other viruses. The network will be positioned to enable rapid vaccine development for CEPI's goal of producing a vaccine in 100 days from the onset of a new pandemic.

2. HEALTHCARE ACCESS

First approval through ACCESS consortium

2.1 A new medicine for people with the progressive eye diseases wet age-related macular degeneration and visual impairment due to diabetic macular oedema, faricimab, was approved in May as the first treatment approved by the UK regulator through the Access Consortium 'New Active Substance Work Sharing Initiative'. This is a collaboration of regulatory authorities including the United Kingdom, Australia, Canada, Singapore, and Switzerland and this product will reach UK patients earlier than in the EU.

Innovative Licensing and Access Pathway

2.2 The first medicine to be awarded an innovation Passport in April 2021 under the Innovative Licensing and Access Pathway (ILAP), belzutifan, has now been authorised via the FDA Orbis initiative for cancer medicines. Belzutifan is licensed for von Hippel Lindau disease, a very rare cancer which affects the kidneys and nervous system. ILAP continues to evolve, focussing on future priorities such as a medical devices pathway and implementing the lessons learned on co-ordinating regulatory and health technology assessment decisions.

Hormone Replacement Therapy supply

2.3 An Incident Management Team was established to ensure proactive and coordinated support to the Government's hormone replacement therapy initiative. Two workshops were held with manufacturers, community pharmacies and wholesalers to set out the regulatory options available to manage supply disruptions. These included processes to expedite regulatory review, importation from overseas markets and the flexibility to move quantities of products between pharmacies.

Vaccines and therapeutics for monkeypox

2.4 We have responded to the recent increase in monkeypox cases, working with companies to support and accelerate access to suitable vaccines and treatments in the UK. As outlined in the Green Book (Immunisation against infectious disease), vaccines designed for smallpox may be used to protect against monkeypox in people who are at risk of exposure to the infection. We are proactively working with the manufacturer and with Health Canada, which has approved this vaccine (known as Imvamune in Canada) for monkeypox, to ensure we have all available data to support the safety and effectiveness of the vaccine the UK. Tecovirimat is a therapeutic approved for use against Monkeypox in the EU. It is not licensed in the UK but we are monitoring the situation closely.

Vaccine studies based on immuno-bridging

2.5 Following the MHRA's role in authorising the first COVID-19 vaccine to be approved using an immuno-bridging approach in place of Phase 3 placebo-controlled efficacy trials, numerous requests for scientific advice meetings have been received from companies wanting to adopt a similar approach for their vaccine candidates. Advice meetings have been held with companies developing COVID-19 vaccines specifically for low and middle-income countries, and those modifying their previously approved COVID-19 vaccines to target new variants of concern.

Quality standards for Advanced Therapy Medicinal Products

2.6 The British Pharmacopoeia (BP) has published a new guideline for Advanced Therapy Medicinal Products on Vector Copy Number. The Vector Copy Number measures the amount of viral genome present within virus particles; it is important to measure this to ensure the quality and safety of a cell therapy product. This guideline builds on the publication of a Flow Cytometry text published last year. The guidance supports innovation in cell and gene therapies by offering practical, phase appropriate advice on quality to stakeholders.

Revision of medical devices regulations

2.7 Work continues to ensure that the Government response to the Consultation on the future regulation of medical devices in the United Kingdom, and supporting transitional arrangements, are published as soon as possible. This is in the final stages of the cross-Government process. Engagement with stakeholders to support the introduction of the new regulatory system is ongoing.

3. PARTNERSHIPS NATIONAL AND INTERNATIONAL

Membership of ICH

3.1 On 24 May 2022, MHRA was welcomed as the 20th member of the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH). The ICH brings together regulatory authorities and the pharmaceutical industry to discuss scientific and technical aspects of pharmaceuticals and develop ICH guidelines, which are adopted worldwide. The Agency's full membership of ICH is a priority for our international activities and will support the international agenda of achieving greater global harmonisation and convergence of pharmaceutical requirements.

Membership of IMDRF

3.2 Since becoming full members of the International Medical Device Regulators Forum (IMDRF), the Agency has been inputting into the Artificial Intelligence Medical Device Working Group and the Terminologies for Categorized Adverse Event Reporting. We are reviewing our membership across all IMDRF working groups to consider how we can play a more active role in shaping the international framework for medical devices.

Access Consortium Clinical Trials Working Group

3.3 We are chairing the Clinical Trials Working Group as part of the ACCESS Consortium, which has met regularly since September 2021. The concept paper for the Group was officially endorsed by all Heads of Agencies on 28 April 2022. Topics included developing common approaches to regulator issues, information sharing and a long-term goal for work sharing on specific trials which will streamline the review of multinational studies.

4. PATIENT SAFETY

Yellow Card enhancements - SafetyConnect programme

4.1 The first major enhancements to the new Yellow Card platform delivered through the SafetyConnect programme were deployed on 31 May delivering on several Independent Medicines and Medical Devices Safety Review (IMMDSR) recommendations. These include the ability for users to update their reports, as well as for MHRA to schedule follow-ups for topics of interest and move towards smart forms where questions are based on the responses provided by individuals. The deployment will enable patients to submit attachments and improve user 'journeys' based on stakeholder feedback.

Risk of leakage from insulin pump

4.2 On 26 May 2022, we issued a National Patient Safety Alert (NatPSA) on the risk of insulin leakage associated with the NovoRapid PumpCart prefilled insulin cartridge in the Accu-Chek Insight Insulin pump, potentially leading to patient harm. Engagement activities with users of insulin pumps and stakeholder engagement activities with diabetes charities and the National Specialty Adviser for Diabetes were undertaken. The Commission on Human Medicine (CHM) and the Devices Expert Advisory Committee (DEAC) advised that patients should be transferred to an alternative insulin delivery device and endorsed the actions proposed by the MHRA to issue the NatPSA. Work will progress with the healthcare system to support implementation of the alert and evaluation of the impact of this action on patient safety. This is a successful example of the new integrated teamwork by Medicines and Devices teams.

Outcome of prosecution

4.3 The prosecution of ITH Pharma Limited for offences under the Medicines Act 1968 and Health and Safety at Work Act 1974 concluded with the company receiving a £1.2 million fine following a guilty plea. This prosecution relied heavily on the evidence and support of the MHRA which was coordinated by the Criminal Enforcement Unit (CEU). This was one of the largest criminal disclosure exercises the CEU has undertaken, which involved identifying and gathering information from across the Agency over a seven-year period. This resulted in tens of thousands of documents being reviewed and assessed.

5. PATIENT INVOLVEMENT

Valproate risk minimisation review

5.1 The CHM has now held two sessions to hear views from patients and stakeholders on the effectiveness of current risk minimisation materials in product information and educational materials for sodium valproate. This is an effective antiepileptic medicine also used for bipolar disorder, and no patients should stop taking valproate without first discussing with their healthcare professional.

Product information for antidepressant medicines

5.2 In light of concerns raised by families and a coroner's request, the CHM has advised on the establishment of an Expert Working Group to consider how risks are communicated in product information in relation to suicidal behaviour. The CHM Expert Working Group review will take into account the views of patients, families and other stakeholders.

6. DYNAMIC ORGANISATION

Agency transformation programme

6.1 Progress continues to be made on the four main aspects of Agency transformation: people, services, technology and finances. An update on current activities was discussed at an All Staff meeting on 31 May 2022, which included a session where five members of the One Agency Leadership Group spoke openly about the challenges of transformation. There was a lively Q&A session and feedback on the meeting from staff has been positive. The people aspects of transformation remain a key priority. With over 90% of roles in the new organisation now filled, the new structure has come into operation from 1 June 2022. Recruitment to vacancies is ongoing, with a focus on the specialty expertise and experience needed for the new areas of responsibility. Key new appointments already made include Ed Palferman – Deputy Director Communications, Penny Wilson– Deputy Director Innovative Devices, and Christine McGuire – Deputy Director Patient Public and Stakeholder Engagement.

6.2 Work continues apace on developing new services, actively involving the members of the One Agency Leadership Group. The priorities include a risk-proportionate approach to established medicines, new pathways for innovative products include medical devices, and a strategic approach to compliance with regulations. On compliance, an innovative pilot project is in progress to drive a more efficient and rapid return to compliance for those organisations subject to action following an inspection. Blogs and guidance have been published to promote the pilot and provide an overview of the pilot process for stakeholders.

6.3 In relation to Technology, we have begun mobilisation of the Regulatory Management System programme, which will deliver the next generation digital technology to enable our patient safety focused regulatory services as a standalone UK regulator. Engagement with internal users has begun to enable a smooth start to the start of the discovery phase in July 2022 once mobilisation has completed. Current activities include stakeholder mapping, agreement of governance and controls building on previous discussions with relevant parties, user research planning, commercial/sourcing approaches and internal team mobilisation.

Health and Safety Annual Review

6.4 The annual review by the Health and Safety Executive (HSE) took place in May 2022 to consider the year's performance by MHRA for its operations at Containment Level 4 in work with high consequence biological agents with major accident hazard potential. The activities carried out by the MHRA are given a high inherent hazard risk ranking score due to the classification, nature, complexity and extent of its work. Using the Enforcement Management Model to assess proactive and reactive interventions and responses to any notifications, the HSE rated MHRA as being broadly compliant in most areas and fully compliant in some areas. More areas were audited and so this is an improvement in the ratings from 2021.

7. FINANCIAL SUSTAINABILITY

Agency Fees Review

7.1 We continue to progress the review of our current fees and aim for a launch of consultation on our new fees proposal in July 2022, with an effective implementation date of 1 April 2023. Currently a market analysis is being carried out to ensure that the proposals are appropriate for new fees and those fee types where an increase beyond inflation is proposed. Once this is complete, we will finalise all documentation required for the launch of a formal consultation process.

Statutory Accounts

7.2 The external auditors, the National Audit Office (NAO), commenced their final audit of the Agency's Annual Accounts in May. The final NAO report will be presented to the Audit and Risk Assurance Committee (ARAC) on Monday 20 June 2022. Work is progressing well to date and we anticipate that the Final Annual Report and Accounts will be laid before Parliament ahead of the Summer Recess.

8. AGENCY PRIORITIES

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

i. Completing the staffing of the new transformed organisational structure with appropriately skilled people in the remaining vacant roles to fully operationalise the 'One Agency' model

ii. Enabling the new One Agency Leadership Group to provide dynamic leadership to realise the current opportunities, including a major review and optimisation of the Agency's services to all our stakeholders, including patients and the public.

iii. Continuing to engage with stakeholders to develop the future medical devices regulations and ensure transitionary provisions are sufficient to support the introduction of the new regulatory system.

iv. Continuing pandemic preparedness work as the Agency's priority on access to vaccines, diagnostics and therapeutics for COVID-19 reverts to 'business as usual'

v. Continuing to develop our national and international partnerships to make the UK an attractive environment to develop and use safe healthcare products, for the benefit of patients and the NHS.

Dr June Raine
CEO
June 2022

Medicines & Healthcare products Regulatory Agency

BOARD MEETING HELD IN PUBLIC

21 June 2022

Title	What are the key requirements of the MHRA in the proposed new Framework Agreement with DHSC?
Board Sponsor	Carly McGurry
Purpose of Paper	Endorsement

What are the key requirements of the MHRA in the proposed new Framework Agreement with DHSC?

1. Executive Summary

1.1 The Framework agreement between the Agency and the Department of Health and Social Care (DHSC) has been updated following a series of substantial changes to the Agency's operations. Although the new Agreement brings the requirements on both partners up to current expectations, the fundamental principles relating to the Agency's independence and the accountabilities of all actors remain similar.

2. Introduction

2.1 We have been working with DHSC to refresh the existing Framework Agreement between the Agency and the department. The Framework Agreement is a requirement on all Executive Agencies and sets out the arrangements to ensure a successful long-term collaborative partnership.

3. Key requirements of MHRA

3.1 As set out in the Cabinet Office guidance[1] on Executive Agencies, MHRA must agree and operate within a Framework agreement with DHSC. Our current Agreement has been out of date for some time, although we agreed with DHSC to avoid interim updates and complete a wholesale refresh when our exit from both the European regulatory system and our Trading Fund status had been completed. The guidance states that the Framework Agreement must set out:

i. the key elements of the policy and resources framework for the agency; the detailed sponsor relationship between the agency and the department;
ii. the respective responsibilities of the Chief Executive, (where relevant) the Chair and Management Board, the relevant minister, and the departmental Permanent Secretary, senior sponsor and Arms-Length Body (ALB) Accounting Officer.
iii. the financial controls and delegations in place, audit and risk arrangements, and processes for reviewing and if necessary, dissolving the agency; and
iv. where the agency has significant relationships with other bodies, the details of these should also be noted.

[1] Executive Agencies: A guide for departments Executive Agencies: A Guide for Departments (publishing.service.gov.uk)

3.2 Much of the content of the draft Framework Agreement is therefore following set precedent, as captured in Managing Public Money and other Cabinet Office guidance relating to public bodies. The template for the Agreement is owned by HM Treasury, who will need to be content with any areas where our agreement varies from expectation.

3.3 In fact, although much of the agreement has been updated to align with current best practice, there has been little change in the fundamental principles of the document. It has been a useful opportunity to discuss and agree with the department how we wish to collectively approach corporate and business planning, as well as to seek to further clarify how we work together to support Ministers with policy advice. The core objectives and accountabilities, however, remain as established, and the Board will be particularly interested in the sections setting out the roles and accountabilities of the Chair, the Non-Executive Directors (NEDs) and the Board in supporting the Accounting Officer.

3.4 We have worked collaboratively with DHSC to develop the draft Framework Agreement, ensuring that best practice is captured, that the Agency is held to the right standards and sufficiently supported in discharging those standards by DHSC. We have had detailed discussions on the proposed accountabilities of Ministers and of the Agency and on the required involvement and actions of both partners in key activities, such as corporate and business planning. We are now content with the draft which will need to progress through formal cross-government clearance.

4. Recommendation

4.1 As set out above, this is a critical governance document for the Agency. Once established, it will provide the framework for much of the rest of the governance we seek to put in place. The Board is asked to endorse the draft of the Framework Agreement with DHSC, in particular the key requirements for MHRA, so that it can be submitted to HM Treasury for final approval.

Carly McGurry
June 2022

Medicines & Healthcare products Regulatory Agency

BOARD MEETING HELD IN PUBLIC

21 June 2022

Title	What are the key priorities in the MHRA Enforcement Strategy and how does this help keep patients safe?
Board Sponsor	Alison Cave
Purpose of Paper	Approval

What are the key priorities in the MHRA Enforcement Strategy and how does this help keep patients safe?

1. Executive Summary

1.1 The structure and operating model for criminal enforcement in the MHRA are undergoing a substantial refresh as part of the agency's transformation programme. The design of the new Criminal Enforcement Unit (CEU) strengthens and refocuses existing capabilities in this area, brings on-stream new capabilities, and bakes-in innovation and disruptive thinking. Its revised operating model and risk-led prioritisation presents an opportunity to bring about a step-change reduction in the criminal threat to the public from medicines and medical devices related offending ('medicrime') over the next three years. This paper describes how the CEU will take the first steps towards realising this strategic ambition during this this transitional year.

1.2 Noting the unit's outline operating model, approach to prioritisation and performance measures, the Board is asked to endorse the three-year strategic mission of the CEU.

2. Introduction

2.1 On behalf of the Secretary of State, the MHRA discharges the bulk of its statutory responsibilities to enforce medicines and medical devices regulations through market surveillance and risk-based compliance work carried out elsewhere in the agency. In exceptional cases, where criminal activity is suspected or identified, including where efforts to bring regulated entities into compliance have been unsuccessful, the CEU can take robust action to address offending. This includes, where appropriate, bringing offenders to justice.

2.2 The CEU is equipped, resourced and empowered to address medicrime offending and, as a component of the MHRA, benefits from its reach into the agency's considerable reserves of technical expertise. The unit also enjoys the unequivocal support of the police service, where access to additional executive powers is considered necessary.

2.3 The CEU's operational remit mirrors the agency's regulatory responsibility encompassing crime associated with all medicinal products. Reflecting the unit's understanding of prevailing criminal threats, the majority of the CEU's active casework concerns the illegal trade in medicines. The threat picture is less clear in respect of crime within medical devices supply chains. Given the breadth and diversity of the sector, the opportunistic nature of criminal behaviour and the pace of technological change, the unit will take steps in 2022/23 to strengthen its understanding in this area and develop a baseline intelligence assessment of the devices component of the overall medicrime threat.

2.4 In respect of both medicines and medical devices, criminal liability can arise because of serious error or omission within the regulated sector. More commonly, the substantial profits available from the illegal sale and supply of falsified and unlicensed medicines attract organised criminal elements that perceive this as a lucrative and relatively low risk crime of choice. Although these are two very different offending models, each requiring a bespoke response, they can expose the public to similar levels of harm if not addressed robustly.

2.5 Both criminal threats and law enforcement doctrine evolve over time. Offenders and those charged with frustrating them are locked in a perpetual arms race. It is therefore good practice periodically to take stock of the prevailing and emerging threat landscape, and to adjust the interdictory response to keep pace with, if not ahead of, contemporary crime problems. The revised focus and operating model set out in this paper are the product of an informal review of the medicrime threat and the agency's response carried out as part of the OneAgency transformation programme.

2.6 Trends observed suggest most medicrime threats have an online element. Indeed, in 2022, the internet is the almost universal route to market for those unlawfully trading in unlicensed medicines. Reducing or removing access to illegally trading websites and web pages could have a significant beneficial impact on the threat to the UK public. In recognition of the ubiquity of the internet-enabled threat, the revised structure of the CEU strengthens the unit's capabilities in this area.

2.7 In any law enforcement undertaking there are quick wins - thematic or tactical threats that may be comparatively low risk and straightforward to address. Where these compete for resources alongside more complex challenges, there is a danger that the low hanging fruit will be dealt with at the expense of more serious and impactful casework. From public protection, value for money and criminological perspectives this is folly.

2.8 It is thus appropriate for the MHRA to focus finite criminal enforcement resources on preventing, detecting and addressing the most egregious medicrime threats to the public. Furthermore, successful interventions at the higher levels of offending can often have a beneficial trickle-down effect downstream.

2.9 In addition to its acute detrimental impact on public safety, medicrime can lead to more subtle, indirect and long-term harm. If left unchecked, it can distort domestic markets, reduce the competitiveness of the UK industry overseas, damage the nation's reputation as a trusted trading partner, erode confidence in regulation and bring about financial loss to individuals and fiscal loss to the economy. As medicrime also causes wider societal harm, contributing to the maintenance of the rule of law is also a key responsibility of any publicly funded law enforcement function.

2.10 Whilst prioritising public safety, therefore, in setting, refining and operationalising its strategic priorities the CEU considers a broad range of harms associated with medicrime. The thematic priorities set out in this paper, and the tactical decisions that implement them on a day-to-day basis, are determined by risk alone rather than by any considerations of complexity or temporal proximity. This ensures the CEU focus is on the 'right' casework rather than on casework that is either 'right here' or 'right now'.

2.11 The strategic mission described in this paper, and its day-to-day implementation by the CEU will make a significant contribution to important outcomes for the public. Aside from the wider benefits outlined above, robustly addressing medicrime helps maintain confidence in the integrity of regulation, ensuring patients continue to enjoy access to medicinal products that are untainted by the actions of criminals.

3. Proposal

3.1 The design of the CEU and its operating model have been informed by progressive thinking within the law enforcement profession. In many ways, the last ten years have seen a new paradigm in which the traditional *react-investigate-prosecute-repeat* approach is being disrupted by something more targeted, holistic and front-foot. The emphasis of the CEU is on proactive reduction of the criminal threat at every stage of the offending continuum, using all available tools and stratagems.

3.2 The work of the CEU encompasses crime prevention alongside more curative criminal justice measures. In pursuit of optimal protections for the public and value for public money, the CEU will use targeted, sustained, proactive and multi-dimensional interventions to design-out offending, where possible, before it happens.

3.3 This will be achieved by exploring opportunities to intervene to reduce or remove the three elements (means, motivation and opportunity) that combine for a crime to occur by:

- disrupting, compromising and dismantling criminal capabilities - removing the means to offend;
- denying offenders the rewards of their crimes - removing the motivation to offend;
- designing-out systemic vulnerabilities and strengthening vigilance within the regulated sector - removing opportunities to offend.

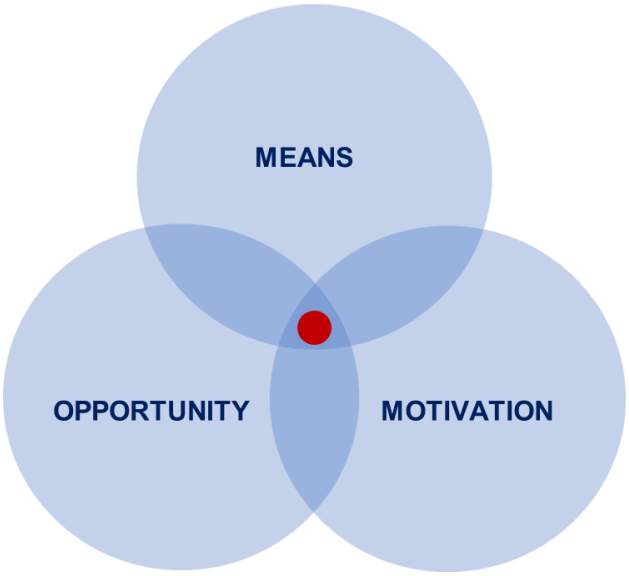

Figure 1: The anatomy of a medicrime offence

3.4 This holistic, 'whole-system' approach to threat reduction offers the very strongest protections for the public and the best opportunity for the CEU to realise its testing strategic ambition. The overall aim is to prevent offending where the unit can, disrupt offending where it cannot, and bring offenders to justice where it should.

3.5 To design threat reduction interventions that deliver a comprehensive response, the CEU applies the '4P' strategic framework which identifies four broad themes of activity:

- **Prevent:** The medicrime threat can be countered in part by diverting, deterring, or displacing offenders from committing crimes. Prevent interventions can make use of statutory powers to deny offenders the profits from their crimes, and targeted communications to increase the perception of apprehension risk. Given the 'slippery-slope' journey from regulatory non-compliance to criminal conduct that exists for a small number of individuals, the CEU also supports and feeds into the delivery of the Agency's compliance strategy led by the Healthcare, Quality and Access Group.

- **Protect**: Medicrime can also be prevented through demand-focused measures. This is sometimes known as 'target hardening'. For the MHRA, 'Protect' interventions might involve raising public awareness of the dangers of purchasing unlicensed medicines and partnering with industry to strengthen safeguards against falsification. The criminological techniques of situational crime prevention can have great utility in the design of both 'Prevent' and 'Protect' interventions, which together create a more challenging environment for offending to occur.

- **Pursue:** Where prevention is not possible, the CEU addresses threats by identifying and bringing to justice those actively involved in offending. While strong threat reduction outcomes are often achieved through investigation and prosecution for medicrime offences, a disruptive effect can sometimes also be achieved by working with public sector partners to identify action that can be taken by others.

- **Prepare:** This supportive and cross-cutting element of the response framework focuses on the strategic imperative to invest time and effort in building and developing counter-medicrime capability both at home and overseas. This can take many forms including investment in people, skills and technology, and strengthening domestic and international relations. Any regulatory response is vulnerable if it fails to invest appropriately to ensure it keeps up with those with malign intent.

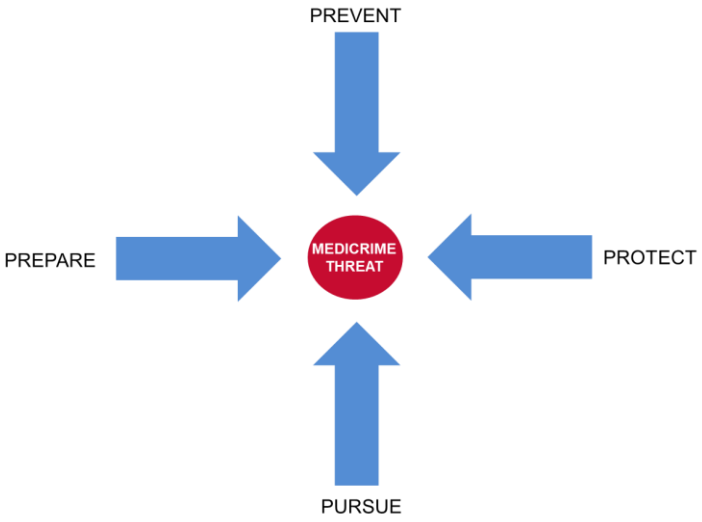

Figure 2: The '4P' strategic response framework

3.6 The refreshed structure of the CEU introduces an 'innovation' capability tasked with identifying, and then leading, coordinating and supporting preventative threat reduction interventions. In common with all aspects of the unit's work, this cannot succeed if done in isolation. Identifying, establishing, maintaining, and leveraging meaningful cross-agency, cross-sector, domestic and international partnerships will be vital to meeting the unit's strategic aim.

3.7 The unit enjoys a particularly strong and productive partnership with UK policing. Local forces routinely provide fulsome support to its pre-planned search and arrest interventions, often committing significant resource upon request. A similarly close relationship exists with the Home Office Border Force in respect of the illegal importation of medicines and medical devices. In addition to the routine vigilance of staff at points of entry into the UK, Border Force colleagues participate enthusiastically alongside the CEU in Operation Pangea, the annual Interpol coordinated period of focus on substandard and falsified medicines.

3.8 The unit determines its strategic and tactical priorities for intervention using a risk assessment tool that provides for consistent, repeatable and intelligence-led prioritisation between and within threats. This facilitates defensible decision-making at all levels. As a consequence of this focus on criminal threats that pose the greatest risk to the public, lower risk offending may often be de-prioritised for intervention.

3.9 Using this tool and based on the unit's understanding of the threat landscape across the agency's areas of responsibility, the CEU's high level priorities for 2022/23 are:

- to reduce the criminal threat from falsified medicines entering the regulated supply chain
- to reduce the criminal threat from the illegal supply of the most harmful UK licensed medicines
- to reduce the criminal threat from the illegal supply of the most harmful unlicensed medicines

3.10 To deliver against these priority threat areas, the Deputy Director (Criminal Enforcement) has set the following operational objectives:

- To establish and maintain a single, compelling and accurate picture of the medicrime threat to support prioritisation and targeted and impactful threat reduction interventions.
- To disrupt, compromise and dismantle criminal capabilities, tools and infrastructure, to remove the means to offend.
- To deny offenders the rewards of their crimes, distorting the criminal business model, to remove the motivation to offend.
- To design-out vulnerabilities and strengthen vigilance, to remove the opportunity to offend.

3.11 The unitary Board rightly expects the MHRA and its component functions to measure performance in a way that is meaningful and purpose-focused. The profession has long wrestled with this challenge, as many traditional quantitative metrics, including crime reporting and conviction rates, whilst readily measurable, offer little real insight into the overall purpose and success of law enforcement effort.

3.12 Acknowledging this perennial challenge and the elusiveness of a perfect means of measuring success, the CEU has adopted a performance framework based on a mix of quantitative and qualitative measures that answer four Key Performance Questions (KPQ). The KPQs are open questions that cover different dimensions of delivery, focusing attention on the core purpose of the unit. Two KPQs address operational delivery and two assess the way in which delivery is achieved:

1. How well does the CEU understand the threat?
2. How well does the CEU respond to the threat?
3. How well does the CEU work with partners?
4. How well does the CEU manage its resources?

3.13 In recognition of the unit's overall threat reduction purpose, the CEU's primary performance measure (as part of KPQ 2) is the Threat Reduction Intervention (TRI). A TRI occurs when an identified strategic or tactical criminal threat is assessed to have been degraded as a result of CEU-resourced activity. The unit may play a leading, coordinating or supporting role in an individual TRI, and a specific threat might be prevented, removed completely, or diminished as a result. Whilst acknowledging the obvious limitations of this measure, the number, impact, focus and spread of TRIs can be considered a reasonable proxy for threat reduction outcomes.

3.15 The revised performance measures of the CEU were piloted throughout the 2021/22 performance year. Almost 2000 TRIs were led, supported or coordinated resulting in:

- the removal of 5.5 million doses of illegally supplied medicines
- prison sentences handed down totalling one-hundred and six months
- the denial of £370,000 in criminal profits
- the removal of more than thirty thousand illegally trading webpages.

4. Recommendation

4.1 The establishment of the CEU on 1st April 2022, signals a new chapter in the story of the MHRA's work to address medicrime. When fully operational towards the end of this year, the CEU will bring renewed focus to this work, better protecting the public we serve, and maintaining a truly class leading law enforcement capability that is the envy of other regulators.

4.2 Noting the unit's outline operating model and approach to prioritisation, the Board is asked to endorse the three-year strategic mission of the CEU.

Alison Cave
June 2022