Medicines & Healthcare products Regulatory Agency

AGENDA FOR BOARD MEETING HELD IN PUBLIC

10:00 – 12:30 on Tuesday 21 September 2021

Chair: Stephen Lightfoot

	AGENDA ITEM	PURPOSE	PRESENTER
10:00	INTRODUCTION 1. What are the priorities for this meeting, how will the meeting run and who are the new Board Directors?	Information	Chair
	2. Are there any Apologies or new Declarations of Interest?	Information	All
	3. What were the minutes and actions from the last meeting?	Approval	Chair
10:20	GOVERNANCE 4. What are the new governance arrangements for the refreshed Unitary Board?	Approval	Chair
10:40	AGENCY PERFORMANCE 5. What are the current issues from the CEO's point of view?	Context	June Raine
11:00	6. What is the current performance of the MHRA on the Balanced Scorecard?	Assurance	Jon Fundrey
11:20	7. What has the MHRA achieved compared to each first quarter deliverable in the Delivery Plan and how will any under-performance be recovered to avoid any impact on the overall two year Plan?	Assurance	Jon Fundrey
11:40	PATIENT SAFETY 8. What assurance can be provided by the Patient Safety & Engagement Committee?	Assurance	Mercy Jeyasingham
12:00	EXTERNAL PERPSCTIVE 9. What questions do members of the public have for the MHRA Board?	-	Chair
12:30	CLOSE OF MEETING	-	Chair

Medicines and Healthcare products Regulatory Agency

Minutes of the Board Meeting Held in Public of 20 July 2021

(10:00am – 12:30pm)

By Zoom Webinar

Present:

The Board

Stephen Lightfoot	Chair
Professor David Webb CBE	Deputy Chair
Dr June Raine CBE	Chief Executive
Dr Samantha Atkinson	Interim Chief Quality and Access Officer
Dr Marc Bailey	Interim Director of NIBSC
Dr Barbara Bannister MBE	Non-Executive Director
Dr Alison Cave	Chief Safety Officer
Amanda Calvert	Non-Executive Director
Professor Bruce Campbell	Non-Executive Director
Jon Fundrey	Chief Operating Officer
Mercy Jeyasingham MBE	Non-Executive Director
John Quinn	Interim Chief Technology Officer
Anne Toni Rodgers	Non-Executive Director
Michael Whitehouse OBE	Non-Executive Director

Others in attendance

Carly McGurry	Director of Governance
Rachel Bosworth	Director of Communications
Natalie Richards	Secretary to the Board and Head of Directorate
Jude Thompson	Executive Assistant to the Chair
Vanessa Birchall-Scott	Director of Human Resources *(for item 8 only)*
Kathryn Glover	Deputy Director, Medicines Regulation and Prescribing, DHSC

INTRODUCTION

Item 1: What are the priorities for this meeting and how will the meeting run?

1.1 The Chair set out his expectations and priorities for this Board meeting held in public which was being live streamed to the registered audience and recorded.

1.2 The Chair welcomed everyone to the meeting, including a broad range of observers representing a range of patient groups, other health bodies, staff and industry.

1.3 The Chair welcomed Dr Alison Cave, who has joined the Agency as the new Chief Safety Officer. The Chair also welcomed Dr Marc Bailey, Interim Director of NIBSC, who was attending in place of the Chief Science and Innovation Officer while the post is vacant.

1.4 The Chair thanked Professor David Webb, Dr Barbara Bannister, Professor Bruce Campbell and Anne-Toni Rodgers, who terms as Non-Executive Directors end on 31 August, for their hard work and guidance to the MHRA during their tenure.

Item 2: Are there any Apologies or Declarations of Interest

2.1 Apologies were received from Cathy Harrison, Chief Pharmaceutical Officer for Northern Ireland; and Greig Chalmers, Head of Medicines Policy Branch at the Scottish Government.

2.2 A Personal Specific Declaration of Interest was made by Professor Bruce Campbell. Professor Campbell attended a scientific meeting in July 2021 with a company called Origin Sciences who are developing new technologies for the diagnosis of colonic and other cancers; a formal arrangement has yet to be finalised however this work will be remunerated. The Chair agreed there are no conflicts of interest with the topics being discussed at today's 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.

3.2 The Board noted that information regarding NICE accreditation of the Agency's Drug Safety Update (DSU) bulletin is included with each publication. The Board also noted that the MHRA Annual Report and Accounts are being laid in Parliament on this day, Tuesday 20 July.

CURRENT CONTEXT

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

4.1 Dr June Raine presented the Chief Executive's monthly report, which covered topics within the four strategic priorities:
(i) Healthcare Access – including updates on COVID-19 vaccine independent testing by NIBSC; COVID-19 vaccines clinical trials; Clinical Trials strategy; the Innovative Licensing and Access Pathway (ILAP); Patient recruitment via CPRD into Atrial Fibrillation virtual clinical effectiveness trial; signing of the first CPRD SPRINT patient recruitment service contract; the NIBSC Annual WHO Standards planning meeting; Agency Horizon Scanning input to NIHR-led workshop on the UK COVID-19 story; Partnerships work including international regulatory collaboration, FDA Project Orbis; Bilateral Conference with the Chinese National Medical Products Administration; and collaboration with the Health Research Authority;

(ii) Patient Safety – including updates on COVID-19 vaccines safety; COVID-19 Tests; safety of acne treatment isotretinoin; chloramphenicol eye drops; National Patient Safety Alerts and Medicines Recalls; a sterilisation issue in relation to medical devices sterilised by Steril Milano; Future Linkage of MHRA Device Registrations; and enforcement activities;

(iii) Dynamic Organisation – including updates on the Delivery Plan 2021-23 and on the Governance Office; and

(iv) Financial Sustainability – including updates on the Upcoming Spending Review and Finance Transformation.

4.2 The Board thanked Dr Raine for her report and provided comments regarding the increasing collaboration with international partners; the importance of contributing to the published literature; the ILAP and opportunities to refine the system, including working with NICE and the Scottish Medicines Consortium and the wider health system to align timelines; the opportunity afforded by the Unique Device Identifier mandate and the importance of prioritising and resourcing this work, and working with the Health Research Authority and the National Institute of Health Research to increase the speed of access of new drugs to patients. An action was taken to review how multiple data sources including Unique Device Identifiers, Registries, NHS data and real world data can be captured and used to strengthen safety surveillance.

4.3 The Board provided further comments regarding research completed with CPRD data and improving GP recruitment; an action was taken to consider alternative ways to increase patient recruitment to clinical trials via CPRD SPRINT, through 'generic' rather than trial specific recruitment.

Action 49: Review progress of patient recruitment for CPRD SPRINT contract as part of a paper to demonstrate how clinical trial approval and recruitment can be accelerated more widely. ***Alison Cave***

Item 5: What is the current performance of the MHRA on the Balanced Scorecard?

5.1 The Board discussed the current performance of the MHRA, presented via the monthly Balanced Scorecard. The Board considered whether the metrics and the commentary provided appropriate assurance that current performance is on track and aligned to the Agency's strategic objectives. The Board provided comments relating to ensuring financial sustainability by realigning the staff base, corporate overhead and technology investment; an action was taken for ARAC to review the Agency's financial performance in the first six months of 2021/22.

Action 50: ARAC to review the Agency's financial performance in the first six months of 2021/22. ***Michael Whitehouse***

5.2 The Board recommended that the balanced scorecard metrics and targets should be reviewed to provide more focus on outcomes, more linkage with the Delivery Plan, more linkage to the Life Sciences Vision, in particular on innovation, and requested greater assurance that resources are available to deliver priorities. The Board provided further comments regarding the greater awareness of the public to report Yellow Cards during the pandemic; ensuring that there is sound justification for targets; the impact of surge resourcing and the need to ensure that resource is deployed in the most appropriate areas of the Agency; and a recommendation to include metrics on areas of investment and divestment.

5.3 The Board were supportive of the progress made on the balanced scorecard however this will need further development to provide full assurance to the Board that current performance is on track and aligned to the Agency's strategic objectives. The quarterly balanced scorecard will be reviewed at the September 2021 Board meeting.

Action 51: 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.
Jon Fundrey

PATIENT SAFETY

Item 6: What progress is being made on the short, medium and long-term deliverables from the Cumberlege Review and how is their impact being measured?

6.1 The Board considered a paper one year on from the publication of the Cumberlege Review (the Independent Medicines and Medical Devices Safety Review, IMMDSR), describing the progress being made on the short, medium, and long-term deliverables from this Review and how their impact is being measured. The Board noted that the Agency fully recognises that a change in culture is a critical step to achieve the change the Cumberlege Report said is needed. The Organisational Development & Remuneration Committee has also been considering the Agency's work on culture and this is the subject of a separate paper to the Board.

6.2 The Board noted the Patient Safety and Engagement Committee has been a pivotal forum to discuss the various issues encompassed in this work, in particular the use of patient reference groups to monitor progress. The Board provided further comments regarding the use of smaller focus groups on specific issues; the need for a deep dive into the Agency's complaints procedures; tools to improve patient engagement; and incorporating the multiplier effect into assessment. An action was taken to review how multiple data sources including Unique Device Identifiers, Registries, NHS data and real world data can be captured and used to strengthen safety surveillance.

Action 52: Review how multiple data sources including Unique Device Identifiers, Registries, NHS data and real world data can be captured and used to strengthen safety surveillance. Incorporate this into the planned review of SafetyConnect. ***Alison Cave***

6.3 The Board provided further comments including a recommendation to seek assurance from an independent expert, which it was noted is currently being procured; ensuring regular engagement with Baroness Cumberlege to provide assurance the Agency is making the required changes; and the importance of the Agency's relationship with the future Patient Safety Commissioner. The Board was assured that the Agency is making progress in this area, however agreed there is more work to be done on the impact of the deliverables.

Action 53: Develop the measures to monitor the impact of the deliverables and activities in response to the Cumberlege Review. ***Alison Cave***

DYNAMIC ORGANISATION

Item 7: What assurance can be provided by the Organisational Development & Remuneration Committee?

7.1 The Board considered an assurance report from the Organisational Development & Remuneration Committee (ODRC). The Board had shared the ODRC's previous disappointment at the pace of change however the ODRC has been assured that the momentum of pace of change has now increased. The Board provided comments regarding the high level specific measures; ensuring resources are invested and divested in appropriate areas of the Agency; and encouraging individual conversations between staff and managers so there is understanding of the case for change, opportunities moving forward and the importance of delivery of the transformation. The Board noted the ODRC assurance report with thanks.

Item 8: What are the strategic priorities for the development of culture and diversity to enable the Future Operating Model?

8.1 The Board considered a paper describing the strategic priorities for the development of culture and diversity to enable the Future Operating Model. The Board noted the Agency's predominant culture is safety and order, however greater emphasis is now needed on innovation, speed and responsibility; none of which can be delivered without leadership. The Board reviewed the culture map and action plan which was developed with the guidance of the ODRC.

8.2 The Board provided comments regarding the importance of allyship as well as leadership; how to measure change in culture; how to properly utilise the resources the Agency has to drive change, and focus on improving processes as well as culture; how to use the transformation programme to identify areas for culture change and to make these changes; the importance of diversity which will help deliver greater innovation; and the need to continue improving the appraisal processes.

8.3 The Board endorsed the priorities in the report to deliver the right environment for change. It was agreed that Board members should individually and collectively demonstrate visible allyship through every engagement opportunity. These are vital building blocks to support the organisation to deliver patient safety.

Action 54: Review the progress and impact of the short, medium and long term deliverables of the agreed Culture, Equality, Diversity and Inclusion plans.
Jon Fundrey

Action 55: Confirm senior executive leadership champions for all Diversity Strands and Staff Inclusion Groups. ***June Raine***

FINANCIAL SUSTAINABILITY

Item 9: What assurance can be provided by the Audit & Risk Assurance Committee?

7.1 The Board considered a report describing the assurance which can be provided by the Audit & Risk Assurance Committee (ARAC). The Board noted that ARAC focused on two topics: financial sustainability, and the change in trading fund status. The previous action was noted that ARAC will undertake a review of the Agency's financial performance in the first six months of 2021/22. The Board noted that ARAC will continue to monitor the preparation for the loss of the Agency's trading fund status as this will have a significant impact on the operation of the MHRA after 1 April 2022. The Board noted that the key actions have been addressed and were assured by this report.

EXTERNAL PERSPECTIVE

Item 9: What questions do members of the public have for the MHRA Board?

9.1 The Board answered a range of questions from members of the public.

ANY OTHER BUSINESS

10.1 The Chair formally thanked Professor David Webb, Dr Barbara Bannister, Professor Bruce Campbell and Anne-Toni Rogers for their expert guidance provided to the Agency as Non-Executive Directors of the MHRA, at their final Board meeting before their terms of office end on 31 August 2021.

ACTIONS FROM MHRA BOARD MEETING IN PUBLIC – 20 July 2021

Action Number	Action	Owner	Date	Status
Carried Forward from previous meetings				
21	ARAC to review governance and risks of the new medical devices regulatory framework in conjunction with PSEC	Michael Whitehouse and Mercy Jeyasingham	~~18/05/21~~ ~~20/07/21~~ 21/09/21	On agenda in PSEC Report
29	Present an Agency Laboratory Strategy to the Board as part of the Agency Science Strategy.	Chief Scientific & Innovation Officer	~~21/09/21~~ 16/11/21	
33	Consult members of the public on the branding of the Yellow Card Biobank.	Alison Cave	21/09/21	Verbal Update
34	The MHRA had a commitment in the Life Sciences Sector Deal 2 to publish a new regulatory pathway for genomic medicines and genomic tests by March 2021. Provide an update on progress of this commitment.	June Raine	~~18/05/21~~ 21/09/21	Verbal Update
38	PSEC and ARAC to agree how to provide assurance to the Board on the development, governance and data standards of SafetyConnect	Mercy Jeyasingham and Michael Whitehouse	~~20/07/21~~ 15/03/22	
39	Implement the approved Communications Strategy with particular focus on measuring trust &communication with HCPs	Rachel Bosworth	16/11/21	
43	A revised assurance and governance framework for the new MHRA organisation should be presented to the Board.	Carly McGurry	15/02/22	
46	The Board's comments on the future development &branding of ILAP, including its potential use for medical devices, should be considered so that a definitive proposal can be presented to the Board for approval.	Sam Atkinson	19/10/21	
New Actions				
49	Review progress of patient recruitment for CPRD SPRINT contract as part of a paper to demonstrate how clinical trial approval and recruitment can be accelerated more widely	Alison Cave	19/10/21	
50	ARAC to review the Agency's financial performance in the first six months of 2021/22	Michael Whitehouse	16/11/21	

51	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	Jon Fundrey	19/10/21	
52	Review how multiple data sources including Unique Device Identifiers, Registries, NHS data and real world data can be captured and used to strengthen safety surveillance. Incorporate this into the planned review of SafetyConnect	Alison Cave	16/11/21	
53	Develop the measures to monitor the impact of the deliverables and activities in response to the Cumberlege Review	Alison Cave	19/10/21	
54	Review the progress and impact of the short, medium and long term deliverables of the agreed Culture, Equality, Diversity and Inclusion plans	Jon Fundrey	18/01/22	
55	Confirm senior executive leadership champions for all Diversity Strands and Staff Inclusion Groups	June Raine	21/09/21	Verbal Update

Medicines & Healthcare products Regulatory Agency

BOARD MEETING HELD IN PUBLIC

21 September 2021

Title	What are the new governance arrangements for the refreshed Unitary Board?
Board Sponsor	Stephen Lightfoot
Purpose of Paper	Approval

What are the new governance arrangements for the refreshed Unitary Board?

1. Executive Summary

1.1 Following the appointment of five new Non-Executive Directors (NEDs) and four new Executive Directors (i.e., Chief Officers), the Board is asked to review and approve the updated governance arrangements for the refreshed Unitary Board. This includes the updated Terms of Reference for the Board, the updated membership of the Board Assurance Committees and the proposed Board schedule for standing items of business.

2. Introduction

2.1 The terms of four of the Board's independent Non-Executive Directors (i.e., Dr Barbara Bannister MBE, Professor Bruce Campbell, Anne-Toni Rodgers and Professor David Webb CBE) came to an end on 31 August 2021 and a recruitment campaign for their replacement was conducted during the summer of 2021. Ministers then appointed the following NEDs onto the MHRA Board from 1 September 2021:

- Dr Junaid Bajwa
- Professor Graham Cooke
- Dr Paul Goldsmith
- Raj Long

Ministers selected these NEDs to complement the skills and experiences of the three existing NEDs whose terms continue until 2023:

- Mandy Calvert
- Mercy Jeyasingham MBE
- Michael Whitehouse OBE

2.2 In addition, as Chair of the Board I took the decision to appoint a non-voting Associate Non-Executive Director from the list of appointable NED candidates presented to Ministers to add some further diversity of experience to the Board. This appointment will also provide Ministers with an immediate option if a NED has to resign before the end of their term as happened in February 2021:

- Haider Husain

2.3 In parallel with the appointment of the new NEDs, an open and competitive recruitment process for the substantive appointment of the four remaining Chief Officer roles on the Executive Committee and the Board has also been conducted. Three of these roles have had interim appointments in place for the last year and I would like to thank Dr Sam Atkinson, John Quinn and Dr Christian Schneider for their support and work in these interim roles.

This senior civil servant recruitment process was led by a Civil Service Commissioner with the involvement of the MHRA Chief Executive, Chair and Director of HR so that the following substantive appointments could be made:

- Dr Marc Bailey, Chief Scientific & Innovation Officer
- Claire Harrison, Chief Technology Officer
- Dr Laura Squire OBE, Chief Quality & Access Officer
- Dr Glenn Wells, Chief Partnerships Officer

These new appointments will join the MHRA Board as soon as they have been released from their current roles and they will join the other three substantive Executives already in role:

- Dr June Raine CBE, Chief Executive Officer
- Dr Alison Cave, Chief Safety Officer
- Jon Fundrey, Chief Operating Officer

2.4 As it is one year since the new MHRA Unitary Board was established, it is now an appropriate time to review its Terms of Reference (ToR), membership of its assurance committees and an outline of its schedule of business.

3. Proposal

Board Terms of Reference

3.1 The current iteration of the Board ToR was developed in 2020 following the Governance Review. This was a significant update on the previous ToR, but as the operation of the Board has continued to evolve over the last 12 months, the arrival of new Board Directors provides a timely opportunity for a further refresh.

3.2 Annex 1 provides an updated summary of the overall accountabilities, responsibilities and routes of assurance between the Board, Executive, Chair and Chief Executive Officer to provide context for new members of the Board.

3.3 Annex 2 includes the proposed and updated Board Terms of Reference, which includes a schedule of matters reserved for Board consideration. Board members will want to be aware of our intention to develop a Board Operating Framework as the new Board undertakes development and induction over the coming months. The MHRA will also be revising its Framework Agreement with DHSC in the next twelve months.

3.4 It is proposed that the Board Terms of Reference are reviewed at the beginning of each financial year.

Membership of Board Assurance Committees

3.5 Following the Governance Review in 2020, the Board has been operating with three assurance committees for the last year:

- Audit & Risk Assurance Committee (ARAC)
- Patient Safety & Engagement Committee (PSEC)
- Organisational Development & Remuneration Committee (ODRC)

It is proposed that these three assurance committees are retained. Each assurance committee will continue to provide a more detailed level of scrutiny in their area of responsibility to provide assurance to the full unitary Board but will not take on or seek to operate any executive responsibilities.

3.6 It is proposed that the Governance Office will work with the Chairs and members of each committee to update their respective Terms of Reference for approval by the Board no later than the beginning of the next financial year.

3.7 It is also proposed that the membership of each Board assurance committee should be made up as follows:

Audit & Risk Assurance Committee

- Michael Whitehouse, NED Chair
- Mandy Calvert, NED
- Dr Paul Goldsmith, NED
- Dr June Raine, Chief Executive Officer
- Jon Fundrey, Chief Operating Officer
- Claire Harrison, Chief Technology Officer

Patient Safety & Engagement Committee

- Mercy Jeyasingham, NED Chair
- Professor Graham Cooke, NED
- Raj Long, NED
- Dr Alison Cave, Chief Safety Officer
- Dr Marc Bailey, Chief Scientific & Innovation Officer
- Dr Laura Squire, Chief Quality & Access Officer
- 2 x Lay Members (*substantive members to be appointed although Susan Bradford & Sara Payne are currently covering the roles on an interim basis*)

Organisational Development & Remuneration Committee

- Mandy Calvert, NED Chair
- Dr Junaid Bajwa, NED
- Haider Husain, Associate NED
- Dr June Raine, Chief Executive Officer
- Jon Fundrey, Chief Operating Officer
- Vanessa Birchall-Scott, Director of Human Resources

Additional Board responsibilities

3.8 As detailed in the governance proposal approved by the Board in October 2020, the Chair will nominate one of the Non-Executive Directors to be Deputy Chair of the Board and nominate another Non-Executive Director to be Senior Independent Director for endorsement by the Agency Board.

The Deputy Chair should be able to deputise for the Chair so that Agency Board business can continue if the Chair is not available for any reason. If the Chair is not a clinician, the Deputy Chair will normally be a clinician (and vice versa) to

provide a good balance of clinical and non-clinical leadership experience for the Board. The Senior Independent Director should have a strong background in financial and/or risk management and will normally be the Chair of the Audit & Risk Assurance Committee. The Chair will consult the Deputy Chair and Senior Independent Director on the operation and effectiveness of the Board, as well as consulting them on any urgent issues which require attention.

3.9 It is proposed that Professor Graham Cooke takes on the role of Deputy Chair of the Board and that Michael Whitehouse continues in the role of Senior Independent Director.

3.10 It is also proposed that Michael Whitehouse take on the role as the NED advisor on the Agency's Corporate Conflict of Interest sub-group, which will provide assurance to ARAC on the Agency's management of conflicts of interest.

3.11 Additional NED responsibilities and "Board Champion" roles will be considered in due course, pending further development of the Agency's Transformation Programme and governance framework.

Board schedule of business

3.12 Annex 3 includes a high-level schedule of standing items for the Board to review over the next twelve months. The Governance Office will work with the Executive Committee and the Board Assurance Committee Chairs to build a forward plan for non-standing items. This will then be incorporated into the planning process at the beginning of each financial year, with quarterly reviews to adapt, align and update as required during the year.

3.13 The schedule sets out the proposed rhythm of assurance committee meetings, which will involve a slight move of one or two meetings already scheduled. Board members will want to note the intention for assurance committees to be scheduled in the first week of the month, allowing a turn around of assurance reports for the Board in the third week of the month, avoiding the lags in reporting that we have encountered previously.

4. Recommendation

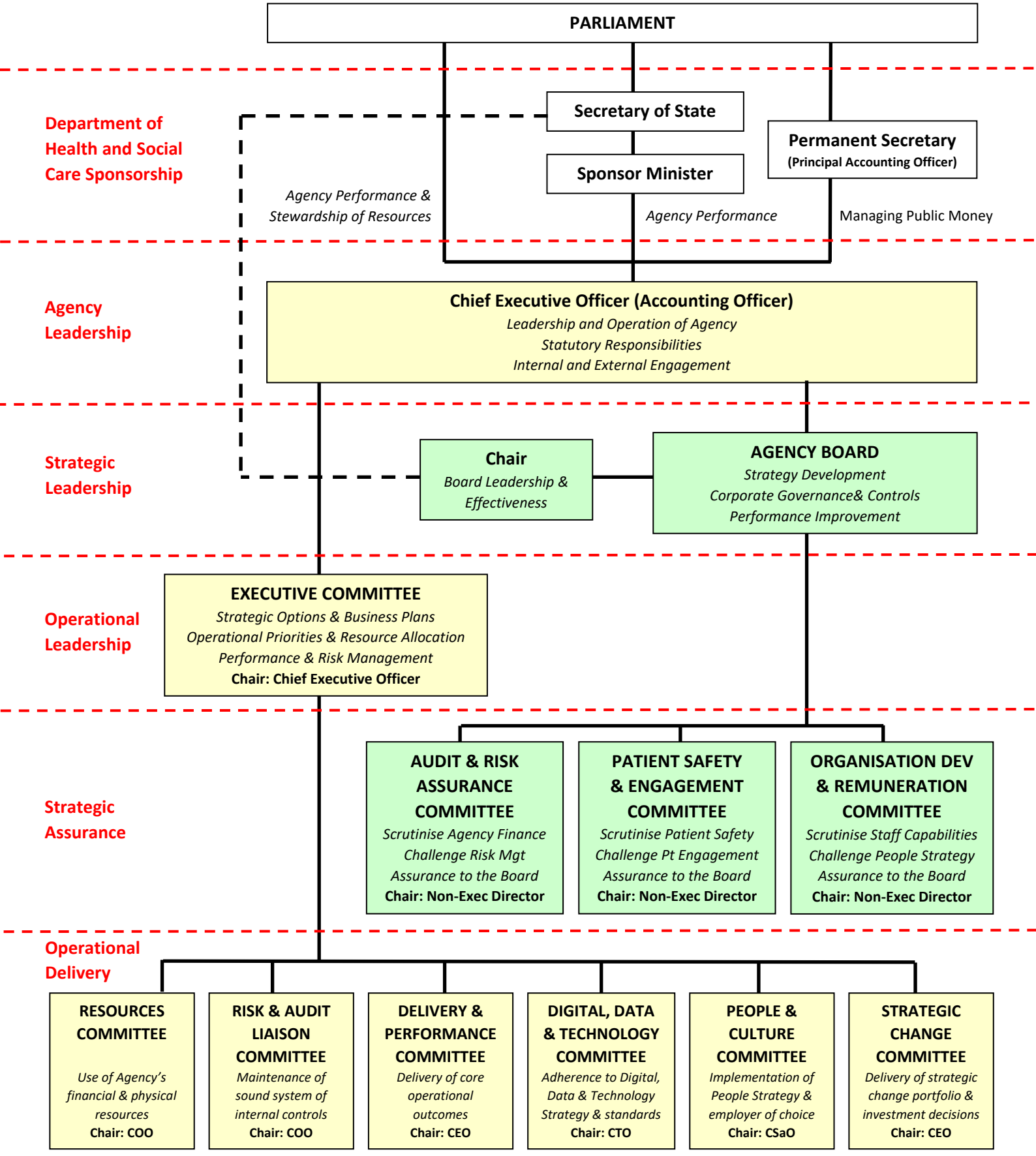
4.1 The Board is asked to:

a. review and approve the refreshed Board Terms of Reference;
b. review and approve the proposed assurance committee membership;
c. review and approve the appointment of the Deputy Chair, Senior Independent Director and NED advisor to the Conflict of Interest sub-group;
d. review and approve the twelve-month Board schedule for standing items.

Stephen Lightfoot
September 2021

ANNEX 1: MHRA ACCOUNTABILITY AND GOVERNANCE STRUCTURE

Approved by the MHRA Board in October 2020 and updated in September 2021



ANNEX 2: Agency Board Terms of Reference

1. Purpose

1.1. These Terms of Reference set out the principles that should underpin the roles and responsibilities of members of the Agency Board, which should be consistent with the Government Code for Public Appointments[1], Code of Conduct for Board Members of Public Bodies[2], and Managing Public Money[3]. Details of the relationship between the Department of Health and Social Care (DHSC) and the Medicines and Healthcare products Regulatory Agency ('the Agency') are defined in the Framework Agreement[4].

2. Purpose of the Board

2.1. The Agency has a unitary Board with an equal number of Executive and Non-Executive Directors, plus a Non-Executive Chair, supported by three Board Assurance Committees.

2.2. The unitary Board is responsible for advising and agreeing the strategic direction of the Agency, endorsing the Agency's recommendations to ministers on key financial and performance targets as set out in corporate and delivery plans, and advising on and monitoring plans to ensure those targets are met. The Board 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.

2.3. The Board has no involvement in any regulatory decisions affecting medicines, medical devices or any other products or services delivered by the Agency. These are the responsibility of the Chief Executive Officer, supported by the Executive Committee.

2.4. Final decisions (and the responsibility and accountability for those) rest with the Chief Executive Officer as the Accounting Officer of the Agency.

3. Responsibility

3.1. The responsibilities and matters reserved for the Board are set out in full in the scheme of delegation annexed to these Terms of Reference.

3.2. The Board is the senior decision-making forum in the Agency. It provides strategic leadership to the organisation and, in support of that:

- Sets the overall strategic direction of the Agency, within the context of Ministerial direction;

[1] https://www.gov.uk/government/publications/governance-code-for-public-appointments
[2] https://www.gov.uk/government/publications/code-of-conduct-for-board-members-of-public-bodies/code-of-conduct-for-board-members-of-public-bodies-june-2019
[3] https://www.gov.uk/government/publications/managing-public-money
[4] https://www.gov.uk/government/publications/dh-and-mhra-framework-agreement

- Approves the Agency's Corporate Plan, Business Plan and shorter-term Delivery Plans, which are designed to support achievement of the Agency's strategic objectives, and monitors performance against them;
- Holds the Executive to account for the performance and proper running of the organisation, including operating in accordance with legal and government requirements and those set out in the Agency's Framework Agreement with DHSC;
- Ensures that effective arrangements are in place to provide assurance, effective risk management, governance and internal control;
- Promotes effective dialogue between the Agency, its stakeholders, the DHSC and patients;
- Encourages and engenders robust and expansive patient engagement throughout the organisation;
- Determines which decisions it will make and which it will delegate to the Executive via the Scheme of Delegation;
- Ensures high standards of corporate governance and personal conduct;
- Monitors the performance of the Agency against core financial and operational objectives; and
- Provides effective financial stewardship.

3.3. The Board does not exercise any line management or executive functions. It does not have any involvement in any regulatory decisions affecting medicines, medical devices, or blood components for transfusion or any other services delivered by the Agency. These are the responsibility of the Chief Executive Officer, supported by the Executive Committee and their staff.

3.4. The DHSC is responsible for assessing the performance of the Chair and the Chief Executive Officer. The Chair is responsible for assessing the performance of Non-Executive Directors and the Chief Executive Officer is responsible for assessing the performance of the Executive Directors.

4. Composition

4.1. The unitary Board is led by a Non-Executive Chair, who is appointed by the Secretary of State for Health and Social Care. The Chair in turn is supported by a unitary Board comprising of not more than 15 individuals.

4.2. Board membership should be formed of up to seven Non-Executive Directors (NEDs), appointed through open competition by the Secretary of State for Health and Social Care, and an equal number of Executive Directors, excluding the Chair. The Chief Executive Officer will appoint the Executive members of the Board from the Executive Committee of the Agency.

4.3. The Chair will nominate a Non-Executive Director to be appointed as Deputy Chair of the Board with agreement from the remainder of the Board. The Deputy Chair should be able to deputise for the Chair so that Board business can continue if the Chair is not available for any reason.

4.4. The Chair will also nominate a Non-Executive Director to be appointed as Senior Independent Director of the Board with agreement from the remainder of the Board. The Senior Independent Director will be a sounding board for the Chair and will also be responsible for evaluating the performance of the Chair on an annual basis, without the Chair present, to provide input into the Chair's annual appraisal with the senior DHSC sponsor. They would also be expected to meet with Board members and act as an intermediary if required.

5. Membership

5.1. The Non-Executive Directors of the Board do not represent any specific customer, sectoral or stakeholder interests. Ministers will take into account the balance of skills when NEDs are appointed so that the Agency Board has the requisite skills and experience profile to deliver the Corporate Plan and Strategy. The primary function of the NEDs will be to provide constructive challenge, strategic guidance, offer specialist advice and hold the executive to account.

5.2. The NEDs will have Terms of Appointment clearly setting out what is required of them, how their performance will be appraised and the duration of their appointment. The Secretary of State for Health and Social Care may terminate an appointment for any reason before the expiry of the fixed period by giving three months' notice in writing. Additionally, a NED may resign by giving three months' notice in writing to the Secretary of State for Health and Social Care.

5.3. The Agency's Executive Directors will be members of the Board and hold full voting rights on the Board. They will be appointed as Senior Civil Servants in their executive roles through the processes and conditions determined by the Civil Service Commission.

5.4. All members of the Board are subject to the Agency's Conflicts of Interest policy and the Cabinet Office's Code of Conduct for Board Members of Public Bodies. Members should pro-actively declare any potential conflicts of interest arising either from business on the agenda or from changes in their personal circumstances.

5.5. When a declaration of a potential conflict of interest is made, the Chair should determine an appropriate course of action, ranging from exclusion for a particular item of business to cessation of membership. Where the Chair has a conflict of interest, the other members led by the Senior Independent Director should determine the appropriate course of action.

6. Quorum

6.1. A quorum for meetings will consist of at least eight members, four of whom should be Non-Executive Directors and four of whom should be Executive Directors, plus a Non-Executive Chair or Deputy Chair.

6.2. If a member of the Board has been disqualified from participating in discussion on any matter by reason of a conflict of interest, they will no longer count towards the quorum.

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

7. Board Assurance Committees

7.1. The Board may set up committees and delegate authority to them, as the Board sees fit. The composition, terms of reference and reporting requirements of such committees shall be approved by the Board. The Board assurance committees currently constituted are:

- Audit and Risk Assurance Committee
- Patient Safety and Engagement Committee
- Organisational Development and Remuneration Committee

8. Frequency of Meetings

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

9. Format of Meetings

9.1. Board Meetings will be held in Public where members of the public will have the opportunity to observe the Board conducting its business via an online broadcast. However, the Board Meetings will not be public meetings and members of the public will not be involved in making decisions at Board Meetings. However, the Chair will provide an opportunity for members of the public to ask questions directly to the Board at each meeting if time allows.

9.2. Where a formal decision is required on a confidential item, a Board Meeting in Committee will be held in private.

9.3. The Board may also meet in a Board Seminar format where there is a more informal opportunity to meet external guests, provide input into the development of new strategies and take time for the Board's own development.

10. Attendance

10.1. The DHSC Senior Departmental Sponsor and representatives from the Devolved Administrations shall have a standing invitation to attend Board Meetings Held in Public and Board Meetings in Committee.

11. Secretariat

11.1. The Board is supported by a Board Secretary from the Agency's Governance Office who should ensure that the Board has the policies, processes, information, time and resources that it needs in order to function effectively and efficiently.

11.2. The Board Secretariat will be responsible for:

- Preparing the agenda in consultation with the Chair;
- Developing and maintaining an effective twelve-month schedule for the Board which enables timely co-ordination between assurance committees and the Board so that all standing business is captured and planned in advance;
- Commissioning Board papers and working with Agency staff to continually improve the quality of papers;

- Circulating Board papers to members and invitees a minimum of five working days before each meeting;
- Producing and circulating draft minutes of the Board meetings to members, within ten working days after the meeting; and
- Maintaining an action log.

12. Delegated Authority

12.1. The Scheme of Delegation is available in Annex A.

13. Board Reporting

13.1. Recordings of Board Meetings Held in Public will be published on GOV.UK, together with the associated Board papers.

13.2. Minutes of the Board meetings will be provided to the Executive Committee and will be made available on the Agency's web page on GOV.UK.

14. Review of these Terms of Reference

14.1. These terms of reference will be agreed by the Board and reviewed at least annually at the beginning of each financial year.

ANNEX A: SCHEME OF DELEGATION

Certain matters are reserved for the Agency Board. The key aspects are summarised as follows:

Function / Duty / Responsibility of the Board	Responsibility of the Executive
Governance & Strategy	
Determining the overall strategic direction of the Agency. Consideration and approval of the Agency's strategic plan.	Preparation of the Agency's strategic plan for consideration and approval by the Board, ensuring early consultation with the Board.
Consideration and approval of formal strategic partnerships with other organisations.	Recommendations to the Board for formal strategic partnerships with other organisations.
Strategic principles governing operational policy relating to the exercise of the Agency's functions, powers and discretions.	Exercise of all the Agency's legal and administrative powers and discretions in furtherance of statutory functions, subject to escalating any high risk/high impact issues in line with the stated risk management approach.
Consideration of the annual Business Plan and associated budget(s).	Preparation of corporate plans and annual budgets in line with the Agency's strategic plan, ensuring early consultation with the Board.
Approval of changes to ToRs for standing committees of the Board, Board Sub-Committees and Executive Committee.	To have regard to the annual review of ToRs for the Board and Executive Committees and bring to the attention of the Board any changed for adoption / approval.
Approval of the Agency's risk appetite, risk management strategy and risk framework, and consideration of reports of the Audit and Risk Assurance Committee, in conjunction with the Accounting Officer.	The CEO as Accounting Officer will maintain the system of internal control and assurance framework within the Agency and provide the Board and Audit and Risk Assurance Committee with assurance on its ongoing effectiveness. Advise the Board and Audit and Risk Assurance Committee as to material changes thereto. Escalation of issues for consideration by the Board in accordance with the Agency's risk management strategy.
Approval of the Agency's overarching scheme of reservation and delegation	To bring to the Board's attention any recommendations for amendments which have come to light as a result of execution of the CEO's wider responsibilities (as delegated in this document)
Approval of Annual Report and Accounts, in conjunction with and support of the Accounting Officer, and following a recommendation from ARAC.	Drawing up the annual report for adoption. Drawing up annual accounts including the annual governance statement for Audit and

	Risk Assurance Committee consideration and Board approval. The CEO will sign the Agency's Annual Report and Accounts as the Agency's Accounting Officer.
Delegate approval of the Agency's counter fraud and security management arrangements to the Audit & Risk Assurance Committee so that the Committee Chair can update the Board on significant issues in their regular Committee assurance report to the Board.	Preparation of such documents and policies to facilitate such approval with due regard to the Agency's stated risk appetite within this domain.
Delegate approval of the internal audit assurance programme to the Audit & Risk Assurance Committee so that the Committee Chair can update the Board on significant issues arising from the work of the appointed auditors in the regular Committee assurance report to the Board.	Reporting to the Audit and Risk Assurance Committee and the Board matters of significance arising from the work of internal and external auditors.
Consideration and approval of aspects of the corporate governance framework, including principles of good governance, corporate values statements, and such other aspects which may arise from time to time.	All matters of organisational below the level of CEO. Delegation of authority to other Agency staff and preparation and maintenance of a comprehensive scheme of delegation for the organisation.
Consideration and approval of appointments to Board assurance committees, following the recommendation of the Chair.	
Financial / People / Operational	
Approval of the Agency's Standing Financial Instructions and financial scheme of delegation.	Preparation of the Standing Financial Instructions in consultation with the Resources Committee and Executive Committee.
Matters which may have a serious impact on the reputation of the Agency or have a political or public sensitivity.	Exercise of all the Agency's legal and administrative powers and discretions in furtherance of statutory functions, subject to escalating any high risk/high impact issues in line with the stated risk management approach.
Significant variations to the approved annual business plan and financial budget, where the variation would have a fundamental impact on the delivery of the Agency's strategy and its statutory responsibilities.	Mitigations and actions to correct variations to the approved annual business plan and financial budget so that assurance can be provided to the Board on the delivery of the agreed plans.
Confirmation of the regular performance reports and information required to provide	Informing the Board of progress in achieving performance objectives and advising of any

appropriate scrutiny and assurance of the Agency's overall performance. The Board may ask the Executive Committee or one of the Board Assurance Committees to review any specific areas of concern in more detail so that recommendations for improvement can then be made back to the Board.	significant variance from the approved operating plans and budget. Informing the Board of any significant issues in the operation of the Agency.
Approval of significant changes to the Agency's organisational structure and People Strategy.	Preparation of the People Strategy and associated policies in consultation with the People and Culture Committee and through the Executive Committee.
The Organisational Development and Remuneration Committee will make recommendations to the Chief Executive on the performance assessment and discretionary rewards for the Executive Directors.	All appointments and all other HR / people issues throughout the Agency.
Legal / Regulatory	
Approval of significant changes in the Agency's regulatory approach or strategy so that appropriate representations can be made to Ministers and the DHSC.	Exercise of all the Agency's legal and administrative powers and discretions in furtherance of statutory functions, subject to escalating any high risk/high impact issues in line with the stated risk management approach.

ANNEX 3: High level Board Schedule - Standing items

	21 September 2021	19 October 2021	16 November 2021	16 December 2021	18 January 2022	15 February 2022	15 March 2022	19 April 2022	17 May 2022	21 June 2022	19 July 2022	16 August 2022
Board Meeting Held in Public Operating Context	CEO report	CEO report	CEO report	**No Board Meeting – time held for Board development**	CEO report	CEO report	CEO report	CEO report	CEO report	CEO report	CEO report	**No Board Meeting – time held for Board development**
Performance Reports	Balanced Scorecard (quarter 1 data) Quarter 1 Delivery Plan Report	Balanced Scorecard (month 5 data)	Balanced Scorecard (quarter 2 data) Quarter 2 Delivery Plan Report	*Balanced Scorecard (month 7 data) (circulated by correspondence)*	Balanced Scorecard (month 8 data)	Balanced Scorecard (quarter 3 data) Quarter 3 Delivery Plan Report	Balanced Scorecard (month 10 data)	Balanced Scorecard (month 11 data)	Balanced Scorecard (annual results 2020/21) Quarter 4 Delivery Plan Report	Balanced Scorecard (month 1 data)	Balanced Scorecard (month 2 data)	*Balanced Scorecard (month 3 data) (circulated by correspondence)*
Assurance Reports	PSEC and ARAC joint meeting report	PSEC & ODRC assurance reports	ARAC assurance report		ODRC & PSEC assurance reports	ARAC assurance report	ODRC assurance report	PSEC assurance report	ARAC assurance report	ODRC assurance report	ARAC & PSEC assurance report	
Board Governance	Board ToR and Committee Membership	Corporate Risk Register	Corporate Risk Appetite		Cumberlege Deliverables (six monthly review)	Health and Safety Review	Committee ToR	Corporate Risk Register	Board ToR	Annual Report	Cumberlege Deliverables (six monthly review)	
Assurance Committee scheduled in month		PSEC ODRC	ARAC	ODRC	PSEC	ARAC	ODRC	PSEC	ARAC	ODRC	PSEC ARAC	

Medicines & Healthcare products Regulatory Agency

BOARD MEETING HELD IN PUBLIC

21 September 2021

Title	What are the current issues from the CEO's point of view?
Board Sponsor	June Raine
Purpose of Paper	Context

Chief Executive's Report to the Board

21 September 2021

This report gives a brief overview of the Agency's current issues since the July Board meeting. The Board is asked to consider and agree the priorities.

'TOP 10' HEADLINES

- On 6th September, we launched a staff consultation on the Agency transformation plan which aims to deliver proactive regulation of innovative healthcare products, regulatory science and data-driven safety surveillance, together with financial sustainability, with patients at the centre of all we do

- The Pfizer and AstraZeneca COVID-19 vaccines have been approved as booster doses, and third doses for use in immunocompromised subjects following expert review of data on efficacy and safety

- NIBSC has now tested and certificated 131 batches of Pfizer/BioNTech, AstraZeneca and Moderna COVID vaccines, the equivalent of over 127m doses available to UK and overseas vaccination programmes

- We are establishing a Clinical Trials Working Group of the International Coalition of Medicines Regulatory Authorities, to take forward the G7 recommendations to strengthen harmonisation and international co-operation on clinical trials

- Oral contraceptives containing desogestrel were reclassified from Prescription Only to Pharmacy availability, enabling greater access to contraception

- The UK Stem Cell Bank has been awarded a £1.2m grant by NIHR to secure the future of the stem cell bank and support development of novel advanced therapy medicinal products

- A project to support artificial intelligence device regulation for improved patient safety monitoring has been awarded funding by the Regulators Pioneer Fund

- We issued alerts regarding Yellow Card reports of myocarditis with COVID-19 vaccines, and continue to monitor suspected adverse reactions in particular in relation to menstrual disorders and use in pregnancy and breast-feeding

- Following the Government's announcement on the 8 July anniversary of the Cumberlege report, we have continued to engage patients in our programme of work and held a further meeting with the DHSC Patient Reference Group

- We have convened three meetings where patients and families gave evidence and were heard by the Isotretinoin Expert Working Group, ensuring that the Group's report will be informed by patients' and families' views on isotretinoin safety.

HEALTHCARE ACCESS

Innovative Licensing and Access Pathway

1. The Innovative Licensing and Access Pathway (ILAP) continues to attract industry interest and we have now received 57 applications for the Innovation Passport designation covering both common and rare diseases. Of the first 25 Innovation Passport applications, 8 expressed interest in entering the US Food and Drug Administration's (FDA) Project Orbis. Recent innovation passport opinions that have published by companies include hypericin for the treatment of early stage cutaneous T-cell lymphoma (CTCL) in adults, APPA in the treatment of osteoarthritis, tideglusib for the treatment of congenital myotonic dystrophy type 1 (CDM1) and UDP-003 in the treatment of atherosclerosis. We proactively call companies who hold an Innovation Passport to develop their Target Development Profile (TDP) and have received three requests for a TDP.

2. A dedicated ILAP patient reference group with 16 representatives has been established to contribute to the decision making for the Innovation Passport designation and other patient activities such as developing the 'Enhanced Patient Engagement Tool'. Interested members of the reference group attended the ILAP steering group as observers in August and a pilot of patient input into innovation passport discussions started in September. The ILAP webpage has been updated to include a new section on the Patient and Public Reference Group. Current partners have engaged with the Association of the British Pharmaceutical Industry (ABPI) ILAP industry group and have heard feedback from a survey to member companies.

New product approvals

3. We sought advice from the Commission on Human Medicines (CHM) on the assessment of several novel medicines and new indications such as products for obesity and dermatological conditions. In July and August there were four new active substances approved: Vericiguat for chronic heart failure; Ponesimod for Multiple Sclerosis relapse; Bimekizumab for plaque psoriasis; and Roxadustat for anaemia. Approvals are expected to be issued for others over the next few weeks, with a shortened evaluation time of around 150 days to enable these medicines to reach patients early compared with the EU process.

COVID-19 vaccines booster doses

4. Following advice from the Vaccines Benefit Risk Expert Working Group on available data, including data from the COV-Boost trial, the COVID-19 vaccines made by Pfizer and AstraZeneca were approved for booster doses and third doses in immunocompromised people, via the Regulation 174 emergency use provision, on 9th September.

5. The Clinical Trials Unit (CTU) has continued to encourage dialogue with vaccine developers, including clinical trials funded by the NIHR. A trial of third dose vaccines in immunocompromised subjects was reviewed and approved in an expedited manner and aims to complement emerging data from a previous prime-boost trial (OCTAVE trial). CTU is also supporting requests for advice from companies with new COVID-19 vaccines that could be used only as booster doses.

COVID-19 vaccine batch testing by NIBSC

6. By the end of August 2021, NIBSC had tested and certificated 131 batches of Pfizer/BioNTech, AstraZeneca and Moderna COVID vaccines, the equivalent of over 127m doses available to UK and overseas vaccination programmes. NIBSC has completed the technical transfer of the Janssen vaccine and will receive batches to test in September. Technical transfer for two further products is nearing completion and will be initiated for at least one additional COVID-19 vaccine in the near future.

7. NIBSC has responded to requests from national control laboratories to both advise on vaccine control tests, as well as to perform contract testing of COVID-19 vaccines. A publication in the Nature-family journal showcases the work undertaken by NIBSC on independent control testing of COVID-19 vaccines: NJ Rose et al. (2021) National Control Laboratory independent lot testing of COVID-19 vaccines: the UK experience. *npjVaccines* 6:100; https://doi.org/10.1038/s41541-021-00368-7.

COVID-19 tests

8. We issued extensions to the exceptional use authorisations (EUA) granted to DHSC (repurposed Innova/Xiamen Biotime test) and Zhejiang Orient Gene for their COVID-19 rapid antigen lateral flow self-test devices. The purpose of the extension is to permit the use of purchased EUA stock until CE marked self-tests are sufficiently available. Zhejiang Orient Gene achieved CE marked status at the end of July 2021 whilst Xiamen Biotime anticipate receiving their CE mark in September 2021.

Influenza WHO Essential Regulatory Laboratories Meeting hosted by NIBSC

9. NIBSC hosted the 32nd Meeting between the World Health Organisation (WHO) Essential Regulatory Laboratories (ERL), of which NIBSC is one, Collaborating Centres and global influenza vaccine manufacturers. This 3-day virtual event brought together key stakeholders from WHO laboratories, vaccine manufacturers and public health bodies to discuss current and pre-empted issues surrounding influenza vaccine production. Important topics such as global virus surveillance and epidemiology, preparation of candidate vaccine viruses, generation and supply of vaccine potency testing reagents, and a review of the current influenza vaccine campaign were discussed. This bi-annual meeting coordinated and hosted by NIBSC continues to ensure that the influenza vaccine community remains able to respond to the threat of influenza and provide these important vaccines globally.

Wider access to oral contraception via reclassification of progesterone-only pills

10. In July, Pharmacy availability of two products (Lovima and Hana) containing desogestrel 75mcg were approved for the first time for oral contraception in women of childbearing age, including adolescents. This followed a public consultation and extensive work to ensure that information to healthcare professionals and women is clear and comprehensible. As part of the reclassification of these products and to minimise risk in the pharmacy setting, training materials for use by pharmacists have been approved to ensure they are aware of the potential risks of desogestrel (and how to minimise these) and are able to advise and manage women appropriately. A Post-Authorisation Safety Study (PASS) will measure the effectiveness of the pharmacist training materials in enabling pharmacist decision-making and establish the ease of access and use of the materials. The PASS will be a survey-based study to acquire pharmacist's views on the training, their understanding of key messages, and their ability to make correct decisions about whether to supply the product or not.

British Pharmacopoeia

11. The British Pharmacopoeia (BP) 2022, legally effective from the 1st January, was published on time at the start of August and contained 25 new monographs, 122 technical revisions and a new supplementary chapter on the use of Analytical Quality by Design Concepts for analytical procedures. These innovative concepts can support the implementation of enhanced science and risk-based approaches to medicines, supporting innovation of analytical methods and understanding of product quality, which therefore benefits manufacturer innovation and patients.

12. The BP's draft guidance on flow cytometry for Advanced Therapy Medicinal Products (ATMPs) was approved for publication by the Chair of the BP Commission in August 2021. This guideline will support those developing these innovative medicines, via the provision of non-mandatory guidance applicable across the product lifecycle, and patients, by supporting the implementation of appropriate assays for the assurance of product quality.

Supply of blood collection tubes

13. On 11 August, DHSC and NHSE/I informed the MHRA of a risk of shortage of supply of CE marked tubes for blood collection marketed by Becton Dickinson (BD) and that continuity of supply is needed to protect the continued delivery of care and safety of patients. BD applied for an Exceptional Use Authorisation to allow use of FDA approved/non-CE marked tubes, and we granted this with conditions, commencing on 20th August until 10th December 2021 or, if sooner, the date when sufficient quantities of UKCA/CE marked alternative product are available. We have participated in regular DHSC stakeholder meetings involving the NHS Supply Chain, NHSE/I and NHS Blood and Transplant along with representatives from the devolved administrations. NHSE/I issued a Supply Disruption Alert via CAS on 26 August.

Updated Good Practice (GXP) Guides

14. The 2022 edition of Rules and Guidance for Pharmaceutical Manufacturers and Distributors (the "Orange Guide") is now in its 11th edition. The guide has been completely updated and is the first edition post the UK leaving the EU. The 2022 edition of Rules and Guidance for Pharmaceutical Distributors (the "Green Guide") will be the fifth edition of the guide. These are currently with typesetters for publication shortly.

PARTNERSHIPS NATIONAL AND INTERNATIONAL

Clinical trials strategy

15. New systems functionality was launched to support the streamlined combined MHRA and research ethics committee review of Clinical Trials of Investigational Medicinal Products. This is a major milestone in creating one seamless online resource for applicants via the Integrated Research Application System (IRAS). From the 31st August, trial sponsors can manage their complete trial lifecycle via combined review using IRAS from initial application through to amendments, safety reporting, end of trial notification and submission of summary results. This new functionality greatly facilitates scale-up with the goal of all applications using combined review by the start of 2022. In July, about 40% of all Clinical Trials of Investigational Medicinal Product (CTIMP) submissions came in via combined review.

16. The MHRA proposed the establishment of a Clinical Trials Working Group to the International Coalition of Medicines Regulatory Authorities (ICMRA) Executive Committee, which was endorsed. We are taking forward establishment of the Group and discussions on the membership, scoping, governance, and outputs have begun. This Working Group initiative will help take forward G7 recommendations and aspects of the Life Science Vision.

Access Consortium

17. The COVID-19 Vaccines and Therapeutics Working Group of the Access Consortium (a coalition of the regulatory authorities for Australia, Canada, Switzerland, Singapore and the UK) has been developing a consensus statement on immunobridging for authorising new COVID-19 vaccines. The Information Technology Working Group met with Accumulus Synergy to discuss their 5 to 10-year roadmap. We have received our second marketing authorisation application under the New Active Substance Work Sharing Initiative which is currently under review.

FDA Project Orbis

18. The MHRA is now a full participant in Project Orbis, a programme involving the regulatory authorities of Australia, Canada, United Kingdom, Singapore, Switzerland and Brazil and coordinated by the US Food and Drug Administration (FDA), to review and give expedited approval to promising cancer treatments. We have completed assessment of several novel products and new indications and sought advice from the CHM. A number of these products are expected to conclude over the next few weeks, and this will shorten the time for these medicines to reach patients by up to several months compared with the EU process.

Inspections collaboration with FDA

19. As a result of our Good Clinical Practice (GCP) collaboration between MHRA & US-FDA, a joint MHRA-FDA paper was published arising from the topics discussed at the joint February 2020 GCP symposium with FDA. This was published in the journal of Clinical Pharmacology and Therapeutics and is the second joint GCP paper with the FDA continuing our high-profile collaboration that brings key issues to industry with a global regulator perspective. An associated Inspectorate blog has also been published to engage with stakeholders: MHRA and US FDA tackle challenging data integrity - MHRA Inspectorate (blog.gov.uk).

Medicines and medical devices used by cosmetic practitioners

20. On the 23rd July 2021, the MHRA launched its first stakeholder workshop with the *Joint Council for Cosmetic Practitioners* (JCCP) following publication of its Memorandum of Understanding. Together we will improve public protection and consumer safety in the aesthetic industry through positive engagement between our two organisations: working towards the promotion of safer medical devices and medicines and examples of best and safe practice within the aesthetic industry. Other selected stakeholders representing aesthetic practitioners also participated in this workshop. The workshop provided an opportunity for an overview of the regulatory role and for MHRA to share details of various aspects of it its work.

PATIENT SAFETY

COVID-19 vaccines

21. As of the 25th August 2021, over 345,000 Yellow Cards of suspected adverse reactions have been reported. For the Pfizer/BioNTech, COVID-19 Vaccine AstraZeneca and COVID-19 Vaccine Moderna the overall reporting rate is around 3 to 7 Yellow Cards per 1,000 doses administered. A weekly report has been published with a focus on trends under investigation. In particular, we have undertaken thorough reviews of:

I. Reports of myocarditis. These reports are extremely rare, and the events are typically mild with individuals usually recovering within a short time with standard treatment and rest, and the product information for the Moderna and Pfizer/BioNTech vaccines has been updated to inform of these reports to advise healthcare professionals and patients to be aware of important symptoms for myocarditis and pericarditis.

II. Reports of menstrual disorders (period problems) and unexpected vaginal bleeding following vaccination against COVID-19 in the UK, also reviewed by the independent experts of the Commission on Human Medicines COVID-19 Vaccines Benefit Risk Expert Working Group and the Medicines for Women's Health Expert Advisory Group, which has concluded that the review does not support a link between changes to menstrual periods and related symptoms and COVID-19 vaccines.

III. Safety in pregnancy and breast-feeding. There is no pattern from the reports to suggest that any of the COVID-19 vaccines used in the UK, or any reactions to these vaccines, increase the risk of miscarriage or stillbirth or harm to breastfed children or affects the ability to breastfeed.

Valproate and Pregnancy Prevention Programme

22. The second report of the Medicines in Pregnancy Registry is due to be published in September. This report has a focus on valproate but has been extended to cover all anti-epileptic drugs. We are working with NHS Digital to produce a digitalised version of the valproate Annual Risk Acknowledgement Form to facilitate compliance with the valproate Pregnancy Prevention Programme. The Commission on Human Medicines has been reviewing the place of valproate in the treatment of bipolar disorder and will consider this issue again later in the year. We continue to work with the NHSE Valproate Safety Implementation Group in its work to reduce the use of valproate in people who can get pregnant and to prevent pregnancies exposed to valproate.

Isotretinoin for the treatment of acne and patients' views on safety

23. The Isotretinoin Expert Working Group (IEWG) held three meetings in July where the Group heard directly from patients and stakeholders regarding the impact of isotretinoin and how to manage the risks. Recordings of these meetings will be included in the final report of the IEWG after being edited to reflect the consent of participants. The views from patients and stakeholders are an integral part of this review and the IEWG gave time to everyone who was interested in presenting. The IEWG held a meeting in August to consider updates on psychiatric and sexual disorders as well as additional written information from patients and stakeholders with a view to making provisional recommendations. A final meeting is planned to agree the recommendations which will be presented to the CHM in October.

Amiodarone

24. Amiodarone is used to treat serious irregular heartbeats. In July the Pharmacovigilance Expert Advisory Group advised on improvement of the product information with respect to diagnosis of pulmonary toxicity which may occur during treatment. The issue had been raised in response to a Coroner's Regulation 28 Report to Prevent Future Deaths which raised a concern about lung imaging to be undertaken when patients are prescribed amiodarone. There will be further reminders to healthcare professionals about the toxicity of amiodarone.

Contamination of Ultrasound transmission gel

25. Investigation of a possible outbreak of infections with certain bacteria (*Burkholderia aenigmatica* and *Burkholderia cepacian)* following use of a non-sterile ultrasound transmission gel found no evidence of these bacteria in their manufacturing facilities. Changes have been made to improve production lines and the manufacturing process as a precautionary measure to reduce the risk of any possible contamination. Public Health England (PHE) is preparing an alert to healthcare professionals to raise awareness of the risks of *Burkholderia* infection in 'at-risk' patients. We are engaging with other ultrasound gel manufacturers that are known to supply to the UK to improve their instructions for use on the safe use of non-sterile ultrasound gels to further reduce any risk to patients.

Medicines Recalls

26. Class 2 pharmacy and wholesaler level recalls were undertaken for batches of irbesartan-containing medicines due to presence of an impurity with mutagenic potential, and for a batch of metformin 500mg/5ml oral solution due to detection of N-nitrosodimethylamine (NDMA) that is above the acceptable limit. In both cases there was no evidence that the impurity has caused any harm to patients. For both recalls, we communicated with patients and the public, including patient representative groups and other organisations across the health sector. This included a recall notice, a media release, social media activity, and email alerts to the Patient Group Consultative Forum and stakeholders. Our communications emphasised the precautionary nature of the recalls.

Falsified medicines

27. Operation Lotus Webinar: There was successful delivery of the 'Protecting the medicines supply chain from falsified medicines' webinar, which represented a shift in our communication approach from reactive to proactive. This is an example of delivering innovative interventions to ensure the UK has a secure supply chain providing high quality products as required by the Agency's 2 year Delivery Plan.

Transition medical device register

28 The MHRA's transition medical device register, built to capture important details (including UDI-DI unique device identifiers) about all medical devices placed on the GB and NI markets by the 1st January 2022, passed its second major grace period on the 1st September 2021. By this deadline, all Class IIb non-implantable medical devices; Class IIa medical devices; in-vitro diagnostics (IVD) List B products and self-test IVDs needed to be registered. By 1st September 1,115,523 medical devices in all Classes were registered. Class IIb medical devices (implantables and non-implantables) have the largest number of registrations so far at 488,283.

52% (148,029) of all the Class IIa medical devices registered in the first 8 months were registered in the month of August as the 1st September deadline loomed. We expect a big increase in the registration numbers for Class I devices as the deadline of 1st January 2022 approaches, and the overall number of registered medical devices is likely to be in the region of 2 million.

Enforcement

29 In July, two overt interventions took place following separate investigations into the illegal sale and supply of falsified medicines. In both cases, the investigations continue. Successful Enforcement Group prosecutions led to custodial sentences totalling seventy-five months imposed on three defendants. In each case, the offenders had been selling unlicensed medicines, including those controlled under the Misuse of Drugs Act 1971. Financial threat reduction interventions to remove criminal profits from the bank accounts of those suspected of involvement in medicines crime resulted in the receipt of funds to reinvest in this work under the Home Office Asset Recovery Incentivisation Scheme. Removing the proceeds of crime from offenders has a significant punitive and disruptive effect and can alter the risk: reward ratio, reducing offender motivation.

DYNAMIC ORGANISATION

Transformation Programme

30 On 6th September an All Staff Meeting was held to launch the Agency Transformation Programme where the Chair and CEO described the objectives of the Agency transformation and the future Agency. During the 45-day consultation period on the detailed proposals for the organisation, there will be further manager briefings and open group sessions for all staff. These opportunities for discussion will continue and be enhanced by local team and individual meetings. There will be opportunities for colleagues to ask questions and to feed in their comments and ideas.

Public Sector Research Establishment status

31 An application by NIBSC for MHRA to obtain Public Sector Research Establishments Status from UK Research and Innovation (UKRI) has been successful and the Agency is now considered eligible to apply to receive funding from a Research Council, unless specifically stated otherwise in the call guidance. This status will last for a minimum of 5 years. This success follows work by colleagues within NIBSC Infectious Disease Diagnostics, who have been supporting NIBSC Business Development and working with the scientific divisions to put forward this bid.

NIBSC 'Meet the Employer' initiative

32 As part of the Science, Technology, Engineering, and Mathematics (STEM) Ambassadors Network, the NIBSC Lead coordinated a call for volunteers to be interviewed as part of the 'meet the employer' initiative. This was run by the Uni Connect Aspire Higher team in collaboration with the University of Hertfordshire, and involved individuals answering some questions about their education pathway and current career at NIBSC. Videos are now becoming available and can be found on the Aspire Higher You tube Channel and outreach website Videos - Aspire Higher (aspire-higher.co.uk).

FINANCIAL SUSTAINABILITY

Fees Policy

33 Work has begun on financial modelling in light of analysis of key activities completed as part of the Size and Shape programme. A baseline (current state) model has been created which identifies fee earning and non-fee earning activities, calculates cost and matches to income. The next step is to update the model to reflect changes to the organisational structure established by the transformation programme and agree the appropriate Agency fee structure. The aim of the model is to ensure that our fees cover our costs, with margin for capital replacement and R&D.

British Pharmacopoeia

34 Sales of the BP publication and BPCRS have continued to grow, and cumulative BPCRS revenue of £1.338M for the April 2021 to July 2021 period is up 7% compared to the same period last year. Cumulative Revenue for the BP publication for the April 2021 to July 2021 period is up 22% compared to the same period last year. These figures correlate to growth in the usage of our standards, representing increased public health impact globally, and improved financial sustainability. The BP 2021 is the highest grossing BP ever, surpassing £3M in sales at the end of July.

Grant funding for the UK Stem Cell Bank

35 The UK Stem Cell Bank has been awarded a £1.2m grant from the National Institute for Health Research (NIHR) to secure the UK Public repository of human embryonic stem cell lines, and provide further high-quality, ‘regulator-ready’ cell lines as starting materials for advanced therapies. The funding will allow the Bank to conduct further characterisation work and safeguard the repository of clinical-grade stem cell lines made available to commercial and academic partners in the UK and around the world. The NIHR grant will begin in July 2021 and fund the core activities of the Bank until June 2024. The Bank will continue to provide its essential services to the advanced therapies community during this time and will expand its activities to better support the development and delivery of novel advanced therapeutics.

Regulators’ Pioneer Fund Award to support artificial intelligence device regulation

36 The Agency has been awarded funds from the second call of the Regulators’ Pioneer Fund (RPF) for a six-month project focused on developing metrics that could signal significant changes in adaptive learning artificial intelligence (AI) algorithms. The project will be managed by the Devices Software Group, with CPRD leading on technical elements and implementation support provided by the University of Brunel. The key driver for this project is the regulatory challenge posed by adaptive AI algorithms that change as they continually learn. The anticipated outputs of the project include development of metrics for algorithm fit to data and performance statistics, and clinical/regulatory guidance on the interpretation of these metrics. The findings will also inform the UK Regulatory Framework for AI software as a medical device.

June Raine
Chief Executive
September 2021

Medicines & Healthcare products Regulatory Agency

BOARD MEETING HELD IN PUBLIC

21 September 2021

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

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

1. Executive Summary

1.1 This paper sets out the commentary to support the Quarter One (Q1) Balanced Scorecard included in the attached appendix.

1.2 The Board is being asked to review the metrics and the commentary before considering whether this provides sufficient assurance that the current performance of the agency is on track and aligned to our strategic objectives.

1.3 The Board is asked to note the following key points:

- Clinical Trials – The COVID-19 pandemic has disrupted clinical trial programmes and has reduced the total number of clinical trial applications being submitted for approval.
- New Active Substances (NAS) – Demand for the approval of NAS has been higher than expected, partially driven by Covid-19 vaccines, with a four-fold increase in NAS applications in Q1 compared to Q4.
- Innovative Licensing and Access Pathway (ILAP) – We have now had a total of 47 ILAP applications with demand not only being higher than expected but continuing to increase.
- Adverse Drug Reactions (ADRs) – ADR volumes increased dramatically in Q4, largely due to COVID-19 vaccines, and we have now seen a small decrease in line with the reduced number of vaccines administered. We have started to use artificial intelligence (AI) technology to help us process the high volume of data.
- Safety Signals – Yellow Card reporting has also increased significantly due to increased public awareness during the COVID-19 vaccination campaign, so we are introducing automation here as well. This will help us to increase signal detection.
- Financial Performance – Good year to date (YTD) performance means that we are now forecasting a smaller financial deficit of £2.3m at the year-end rather than the budgeted £6.0m deficit for 2021/22.

2. Introduction

2.1 In recent months the MHRA has been developing a Balanced Scorecard to summarise the monthly performance of the agency against key measures related to its strategic goals. The development work on this new reporting system is still ongoing and the latest iteration of the report is included in this paper.

2.2 This report has been updated with data for Quarter 1 (ie 1 April 2021 - 30 June 2021) and compared with targets and previous quarters where possible.

2.3 The targets have been discussed with the operating divisions, the Delivery & Performance Committee (DPC) and the Executive Committee (ExCo). These are presented in the scorecard for the first time and some targets are still missing as we do not have prior year data on which to base them. It was agreed at ExCo that further work is required to refine these targets as they will help to set the standards and the right level of challenge throughout the agency.

3. Commentary

3.1 Patient and Public Involvement

Public Communications Engagement and Reputational Index

These are some of the newest metrics and are still in development. However, the Communications Team has had approval from the Resources Committee to fund the development of the new Reputational Index.

Positive Media Sentiment

This measure is only available in arrears up to Quarter 4 (ie 1 January 2021 – 31 March 2021) and this is showing a universally positive media response to the agency's activities to this date.

3.2 Scientific Innovation

Clinical Trials

We are aware that companies have flagged the difficulty in setting studies up following the disruption and backlogs in clinical services caused by COVID-19. This is not a regulatory issue but a practical one so the MHRA Clinical Trials Unit (CTU) is expediting support to facilitate the re-start of paused studies. A cross-agency UK Clinical Research Recovery, Resilience and Growth (RRG) programme has also been set up to drive the managed recovery of multi-site studies over the next 12 months. As the pressures of the pandemic ease, the UK will manage the recovery of research across all phases, therapy areas and treatment types, with COVID-19 becoming one speciality among a diverse research portfolio. Working with commercial and non-commercial funders, the National Institute of Health Research (NIHR) will sequence the rapid recovery of selected studies across a range of conditions and ensure the UK is able to deliver the levels of activity needed to contribute to global studies.

The MHRA targets for clinical trial applications are based on expected activity for First In Human (FIH), Novel Product and All Other clinical trials with an encouragingly positive trend in First In Human trials in Q1.

Grant Success Rate and Research Papers/Publications

These targets will be changed to actuals rather than estimates and should be included for next quarter.

CPRD population coverage

A small growth target has been set this year with further growth planned in future years.

3.3 Healthcare Access

Early Access to Medicine Scheme (EAMS)

EAMS was launched in April 2014 and has remained an important regulatory flexibility for early access to new medicines. Despite the end of EU transition and the introduction of the ILAP, the Promising Innovative Medicines (PIM) designation applications have remained stable for this scheme. A future public consultation on the operation of EAMS in Human

Medicines Regulation may result in significantly more interest towards the end of the reporting year. The target has been based on expected activity.

Paediatric Investigation Plan (PIP)

The PIP volume has increased since April 2021. It is not possible to explain the trends at this stage as the PIP submissions were only introduced in January 2021 and there was a large initial submission volume towards the end of the Q1 2021 reporting period. Data is being sourced for future targets.

Standard Sales Volume

The National Institute of Biological Standards & Control (NIBSC) sells flu and non-flu biological standards (ie reference materials) and work is ongoing to set appropriate targets. The British Pharmacopoeia (BP) sales target is based on prior year actuals.

New Active Substances (NAS)

National Applications (excluding Orbis): This is new work for the agency as a result of leaving the EU. The volume of full national applications is higher than anticipated (just under 30% NAS have been submitted independently to GB) and includes the COVID-19 vaccines. NAS applications are handled as high priority alongside EAMS and ILAP, which has diverted resource from other national work. There is no previous data to create a target for NAS at this stage.

Orbis: This route is limited to oncology products and is used by one or two products almost every month. These are high priority applications and they are progressed in line with the timetable agreed with our international regulatory partners in the Orbis programme.

European Commission Decision Reliance Procedure (ECDRP): Determination volumes will closely match receipts as EC decisions from recent applications come through with a typical time lag of 6 – 8 weeks. Approximately 25% of these cases require claims of orphan designation to be verified.

Innovative Licensing and Access Pathway (ILAP): This was launched January 2021 and has surpassed expectations in terms of its attractiveness to industry. The first step, the Innovation Passport designation, is the gateway to the future activities in the ILAP and application numbers have steadily increased during the first months of operation. Since launch we have had 47 applications in total.

The target of 40 Innovation Passport applications and 20 Target Development Profile (TDP) meetings was based on the expected activity in the first year.

Device Registrations

Huge numbers of medical devices are currently being registered and the data is not yet sufficiently reliable to create a robust target.

Variations

National Applications: The volume of complex variations (Type II) received is slightly above volumes from last year at 90-100 per month. The rate of determinations does not currently match volumes received and consequently a backlog of assessments is building due to resource demand on higher priority work. Targets are based on prior year volumes.

European Commission Decision Reliance Procedure (ECDRP): Volumes received are settling at around 80 per month; determinations continue to remain in line with demand as expected given the minimal resource required to triage and rely on the EC decision.

Orbis: The variations to extend indications for oncology products are handled in line with the timescales agreed with our other international regulatory partners in this programme.

Generics

National Marketing Authorisation (MA) Applications: Volumes received each month are very variable but on average slightly above receipts from last year. The rate of determinations does not currently match volumes received due to a backlog of phase II assessment responses. This is partly due to the very high level of applications received in the latter months of 2020 as they progress through assessment. Resource for these applications has now been refocused to deal with responses so that more applications can be determined. Targets are based on prior year volumes.

European Commission Decision Reliance Procedure (ECDRP): The volume received to date this year is small – only 29 compared with 213 national applications. Determination volumes will more closely match receipts as EC decisions from more recent applications come through (typical lag is 6 – 8 weeks). Minimal resource is required for these applications.

3.4 Patient Safety

Adverse Drug Reactions (ADRs)

Volumes of ADRs associated with COVID-19 vaccines have plateaued in line with reduce numbers of vaccines being administered, which is reflected in the small decrease in volumes of ADRs on the balanced scorecard. Steps taken to automate data capture (including AI) have helped us process this high volume of reports.

As a result of the increased awareness of the Yellow Card Scheme from the COVID-19 vaccination campaign there has been a sustained increase in non-COVID-19 ADR reports. Non-COVID-19 volumes received to date in 2021 are approximately one third higher than in 2019, which was the previous peak, and reverses a decline seen in 2020 associated with the COVID-19 lockdown and reduced healthcare system contacts.

A significant workload remains in the reclassification of cases and processing follow up reports as well as signal detection, assessment and management of enquires. The target was based on prior year data and will need to be reviewed.

Devices Adverse Incidents

The adverse incident figures showed a 23% rise in Q1, which could reflect the increased engagement with industry on the future device regulations, future vigilance transparency and work encouraging manufacturers to use the correct electronic report forms. The target was based on prior year data and will need to be reviewed.

Adverse Blood Reactions

The decline in reactions in Q3 and Q4 of last year and in Q1 of this year should be assessed with a fair amount of caution as there are multiple factors that affect this figure especially regarding the cancellation of operations due to the COVID-19 pandemic, staff shortages due to an increase in infection rates and surgical and oncology planning within NHS Trusts. The target was based on prior year data and will need to be reviewed.

Safety Signals

There has been a significant increase in Yellow Card reporting since December 2020 when the COVID-19 vaccines were first authorised for use. It has been challenging to resource the processing of these reports to make them available for signal detection as early as possible. A number of technical solutions have been put in place in order to facilitate this. We are now auto-committing reports to the database to make them available as soon as possible for signal detection. The volume of signals has continued to increase when compared to previous months. The target will not be set until a more stable trend has been established.

Safety Communications (Comms)

The number of medicines safety topics was more stable for Q1 of 2021/22 after an unusual peak in communications for Q3 of 2020/21. Key topics in Q1 of 2021/22 included advice on levothyroxine for thyroid disorders and CDK4/6 inhibitors for cancers.

3.4 ***Dynamic Organisation***

Full Time Equivalents (FTE)

The number of full time equivalent staff in post in Q1 was almost identical to the number in Q4 of last year, although this was 4% lower than the Q1 budget due to restrictions on recruitment until the new organisational structure had been agreed. Future targets will be based on the expected transformation headcount.

Key Project Milestones

The intent is to develop a metric that demonstrates the reliability of project delivery within the agency, but this is not yet sufficiently robust so no target has been set and this requires further development.

People Engagement Score

This measure requires a quarterly pulse survey to be conducted among staff and this is still in development.

Indexed Productivity

This is another new measure in development and it is expected that this will be included in the next version of the scorecard.

3.5 **Financial Sustainability**

Operational Financial Surplus/Deficit

The Q1 operational surplus of £5.7m is £6.7m ahead of budget. Currently £3.7m of this variance is due largely to the delayed timing of expenditure. However, a reduction in recruitment has led to a £2.0m saving in staff costs which is expected to continue throughout

the year. This has also reduced the annual forecast from a £6.0m deficit to a £2.3m deficit for the year. The target is based on the agreed annual financial budget.

Corporate Overhead %

Corporate overheads reduced to 30% of MHRA expenditure in Q1. This is lower than expected but is largely driven by lower information technology costs which are expected to increase throughout the year. The target is based on the agreed annual financial budget.

Cash Balance – Available Reserve

Despite expecting to use the majority of our financial reserves this year the agency's cash balance has actually increased by £14m in Q1 to £93m. This is due to receiving the service fee for the year but also due to lower operational, staff and change costs than expected. Considering these changes, the Finance Team is currently undertaking a reforecast so we have a better understanding of the likely year-end balance. The target is based on the agreed annual financial budget.

Non-Pay Savings

Non-pay savings relate to the Commercial project to reduce non-pay costs via contract negotiations and the removal of unnecessary expenditure. No savings have been confirmed to date but opportunities have now been identified that total £7m of savings versus a target of £6m over two years.

Cashable benefits

Data is included on the Balanced Scorecard but this data is not reliable and needs to be developed further.

4. Recommendation

4.1 The Board is being asked to review the metrics and the commentary before considering whether this provides sufficient assurance that the current performance of the agency is on track and aligned to our strategic objectives.

Jon Fundrey
September 2021

Patient & Public Involvement

Public Communications Engagement (SAMPLE DATA ONLY)

160

KPI

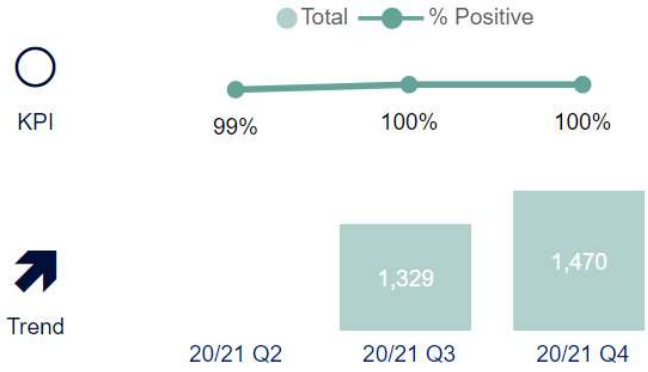
Trend

Positive Media Sentiment

100.0%

KPI

Trend



Reputational Index (SAMPLE DATA ONLY)

0

Goal: 0

KPI

Trend

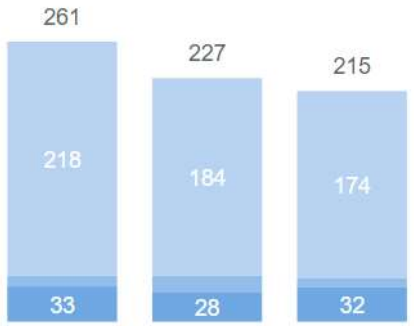
Scientific Innovation

Clinical Trials

Normal
174
Target: 184
KPI: ▼ Trend: ➘

Novel
9
Target: 10
KPI: ▼ Trend: ➘

FIH Approvals
32
Target: 20
KPI: ▲ Trend: ➘



Grants % Success Rate

Grants Applied For
£5.75M
KPI: ○ Trend: ➔

Grants Received
£2.12M
KPI: ○ Trend: ➔

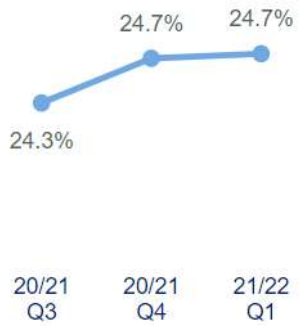
% Success
37%
Target: 8%
KPI: ▲ Trend: ➔

Research Papers - Impact Score / 100 (SAMPLE)

100
Target: 90
KPI: ▲ Trend: ➔

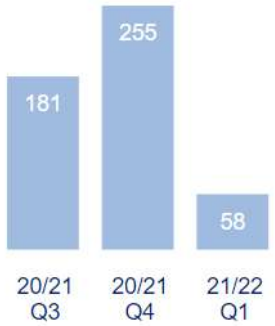
CPRD UK Population Coverage

24.7%
Target: 25.0%
KPI: ▼ Trend: ➚



Publications using CPRD Data - FinYTD

58
KPI: ○ Trend: ➘



Healthcare Access

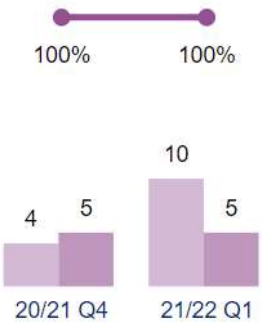
EAMs - PIM-D Applications

Received
10
Target: 6

Granted
5

% Positive
100%

KPI ▲ Trend ↗
KPI ○ Trend →
KPI ○ Trend →



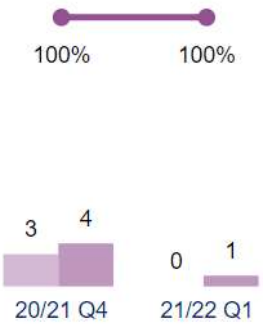
EAMs - EAMs SO Applications

Received
0
Target: 3

Granted
1

% Positive
100%

KPI ▼ Trend ↘
KPI ○ Trend ↘
KPI ○ Trend →

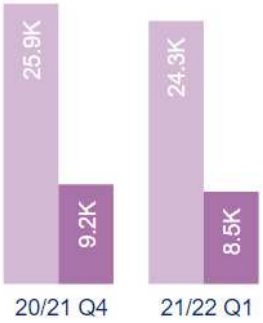


Standards Sales Volume

NIBSC (Non Flu)
24,324

BP
8,538
Target: 8,700

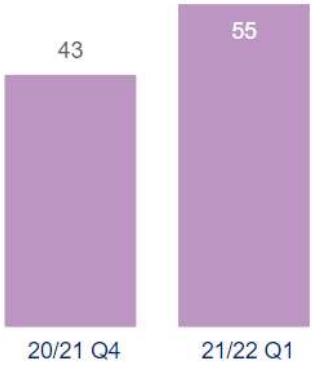
KPI ○ Trend ↘
KPI ▼ Trend ↘



PIPS Volume

55

KPI ○
Trend ↗



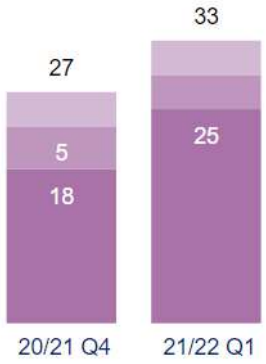
Healthcare Access

NAS - Applications Received

National (PL-GB/PL UK)
4
KPI Trend

Orbis/Access
4
KPI Trend

EC/MRDC Reliance
25
KPI Trend

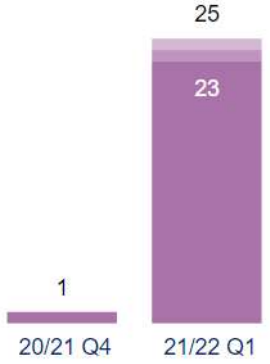


NAS - Applications Determined

National (PL-GB/PL UK)
1
KPI Trend

Orbis/Access
1
KPI Trend

EC/MRDC Reliance
23
KPI Trend



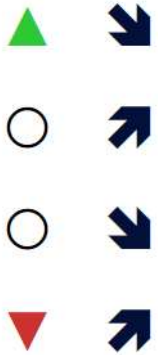
ILAP Passport Applications

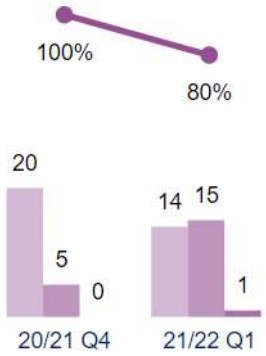
Apps Received
14
Target: 10

Apps Determined
15

% Positive
80%

TDP Meeting Requests
1
Target: 5



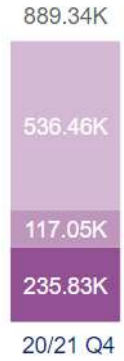


Device Registrations

Deadline 01/05/21
536,459
KPI Trend

Deadline 01/09/21
117,051
KPI Trend

Deadline 01/01/22
235,833
KPI Trend



Healthcare Access

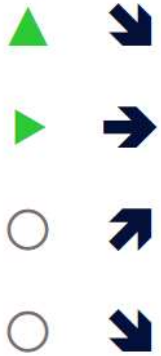
Variations - Applications Received

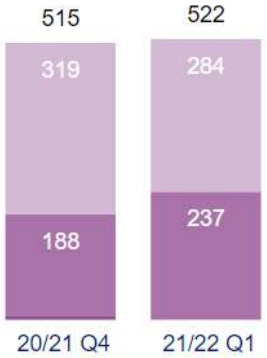
National (Std + Complex)
284
Target: 270

Type II Ext Complex
0
Target: 0

Type II ECDRP
237

Type II Orbis
1





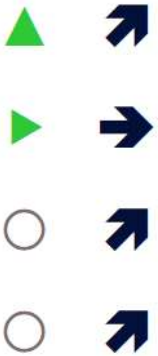
Variations - Applications Determined

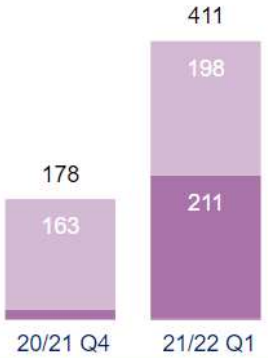
National (Std + Complex)
198
Target: 189

Type II Ext Complex
0
Target: 0

Type II ECDRP
211

Type II Orbis
2

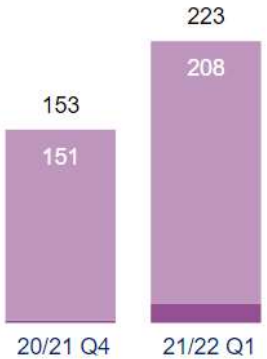




Generics - Applications Received

National MAs
208
Target: 168

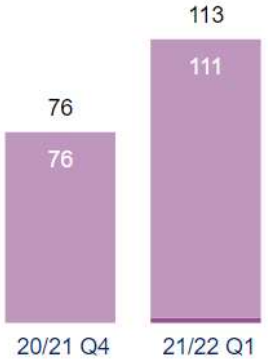
EC/MRDC Reliance
15



Generics - Applications Determined

National MAs
111
Target: 57

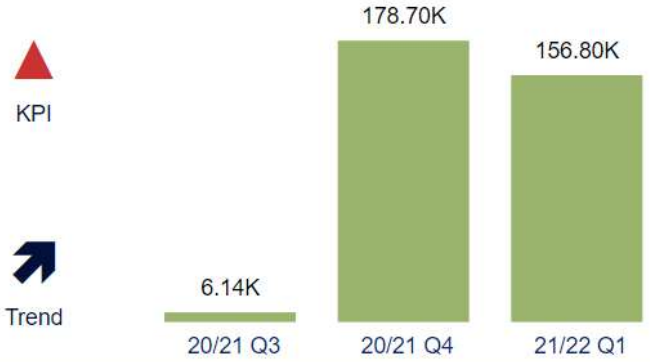
EC/MRDC Reliance
2



Patient Safety

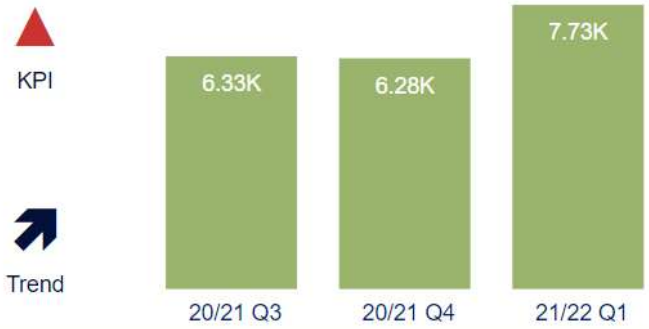
Adverse Drug Reactions

156,797
20/21 Q1: 8,133 (+1827.91%)



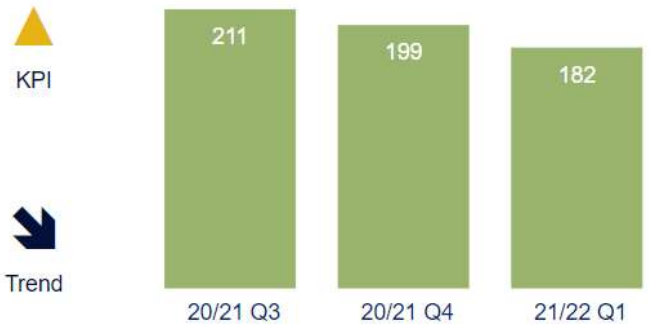
Devices - Adverse Incidents

7,729
20/21 Q1: 4,287 (+80.29%)



Adverse Blood Reactions

182
20/21 Q1: 165 (+10.3%)

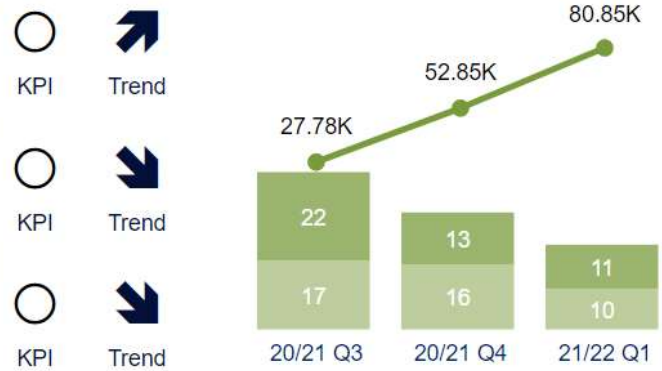


Patient Safety Interventions

Major Signals
80,850

Manuf Safety Comms
11

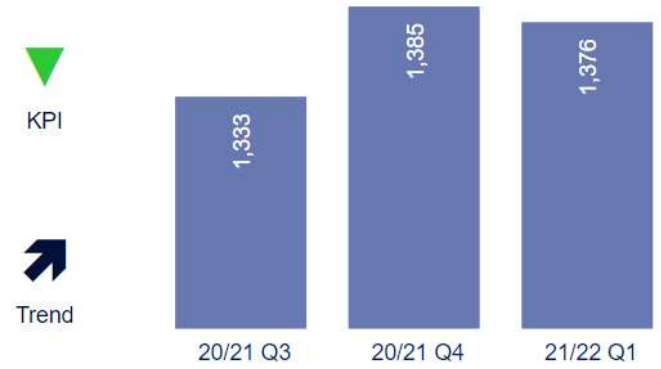
MHRA Safety Comms
10



Dynamic Organisation

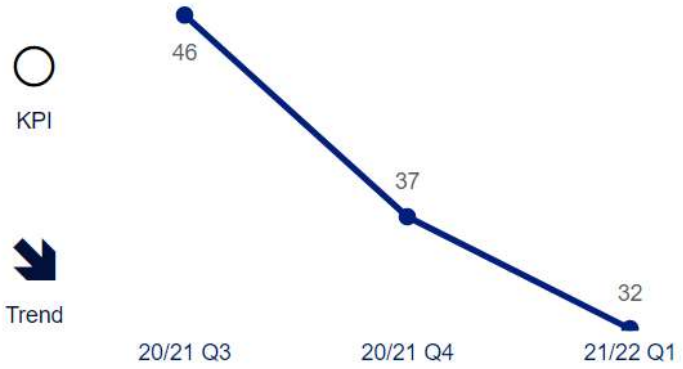
FTE

1,376
Budget: 1,437 (-4.24%)



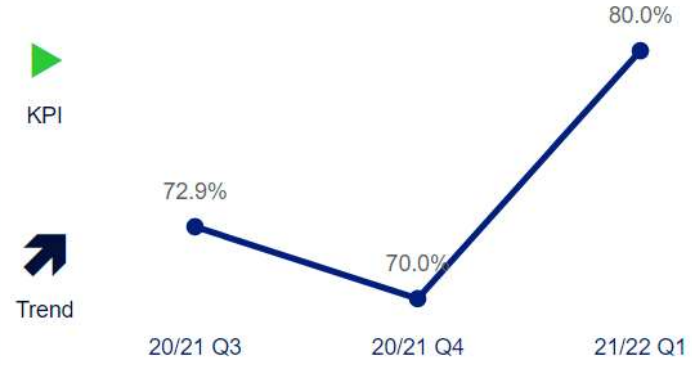
Key Project Milestones Average Days Slipped

32



People Engagement Score (SAMPLE DATA ONLY)

80.0%
Target: 80.0%



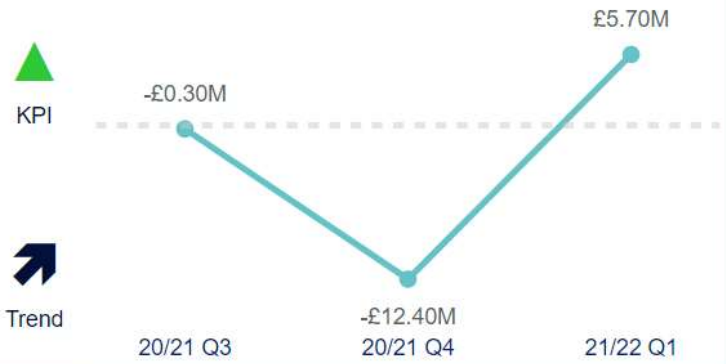
Indexed Productivity (SAMPLE DATA ONLY)

101
Target: 100

Financial Sustainability

Year To Date Operational Surplus/Deficit

£5.70M
Budget: -£0.96M



Corporate Overhead %

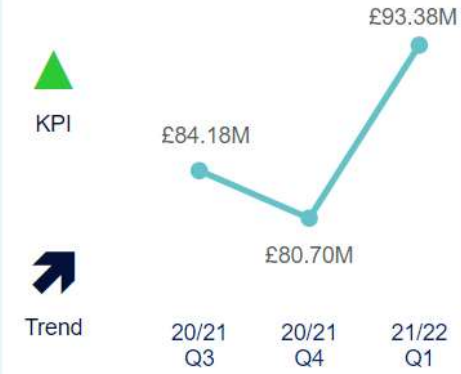
29.4%
Budget: 30.9%

Maintenance Costs
2.0%
Budget: 2.8%

TD3
11.3%
Budget: 13.6%

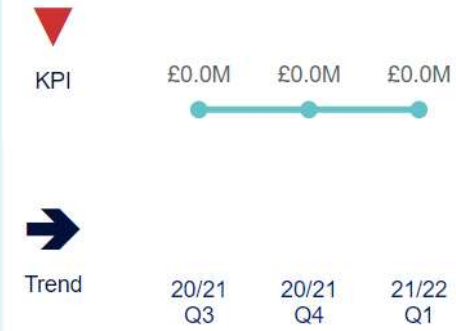
Cash Balance - Available Reserve

£93.38M
Budget: £81.43M



Non Pay Savings

£0.00M
Budget: £0.75M



Cashable Benefits (12m Rolling) (SAMPLE DATA)

£0.75M

Medicines & Healthcare products Regulatory Agency

BOARD MEETING HELD IN PUBLIC

21 September 2021

Title	What has the MHRA achieved compared to each first quarter deliverable in the delivery plan and how will any under-performance be recovered to avoid any impact on the overall two-year plan?
Board Sponsor	Jon Fundrey
Purpose of Paper	Assurance

What has the MHRA achieved compared to each first quarter deliverable in the delivery plan and how will any under-performance be recovered to avoid any impact on the overall two-year plan?

Executive summary

1. This the report on progress against the Delivery Plan for the first quarter (Q1) of the reporting year. The Executive Committee (ExCo) has concluded that despite challenges facing the Agency, good progress is being made. A revised reporting process is being implemented using a Red Amber Green (RAG) methodology; peer review and remedial action has also improved the prognosis of several Amber rated deliverables.

2. Overall, there are 66 items in the 2021–2023 Delivery Plan, and at the end of the Q1 review process, 49 were rated as Green, 13 as Amber and 4 as Blue (complete). The completed items are ministerial clearance of and embedding the Delivery Plan in staff objectives; revising our NICE partnership agreement with a detailed package of work programmes; and delivering a new International Strategy and Culture Action Plan. As this is the first quarter report, most of the focus has been on reviewing the action plans to address Amber items. Monitoring will be important given the pressures expected over winter and from organisational redesign. More work is planned on benefits realisation and being more clear about what success looks like. The Board is asked to note the ExCo's conclusion and provide any comments that they might have.

Introduction

3. The Executive Committee (ExCo) and its Delivery and Performance Committee (DPC) have improved the Agency's performance reporting process to allow for more active management of delivery. Peer review of progress on delivery and action plans have been agreed for each Amber item. Accountability for reporting has been put at a more senior level and a link has been made to the new corporate risk process. The new reporting process has been successfully trialled for Q1 and is helping to ensure the ExCo maintains a good grip on the implementation of the Delivery Plan.

Discussion

4. An overall status update by Delivery Plan priority and objective is below. This provides an overview of confidence in delivery and an orientation, highlighting where the pressure points are and the Amber items. For assurance, details on the Amber items and the action plans that have been agreed to bring them back to Green before their deadlines is provided, along with a summary of performance on what was due for delivery in Q1.

Delivery Plan Priorities and Objectives	RAG
PATIENT INVOLVEMENT (underpinning objective) **1. Deliver better patient and public involvement to ensure we put patients first**	
When the plan was published 23 deliverables were flagged as examples of work with particular patient interest, alongside the work on culture change that cuts across all of our work. As this objective is underpinning these deliverables feature in other objectives (and are all asterisked in annex A). Of the 23, 16 were Green and 7 were Amber in Q1 – these are underlined below. These items will continue to be monitored and the governance of work associated with the IMMDSR response continues in parallel and will help draw key stands together.	G/A
SCIENTIFIC INNOVATION	G
2. Deliver public health impact, world-leading research innovation and a unique proposition	G
4 deliverables – 4 Green	
3. Overhaul clinical trials system to support innovation and reduce time to approval	G
10 deliverables – 9 Green, 1 Amber namely: • "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." (Devices)	
HEALTHCARE ACCESS	G/A
4. Develop and deliver future strategy and approach for access to medicines and devices	G
13 deliverables – 11 Green, 2 Amber namely: • "Put in place new legislation [this year] to ensure safe access to innovative products and to protect public health: timings agreed and public consultations begin from Q1, 2021/22." (Policy) • "Resolution of any live regulatory issues following EU transition by Q1, 2022/23." (Policy)	
5. Establish a new devices legislative framework to support safe innovation and ongoing access to products	A
3 deliverables – 3 Amber (note it's one multistage project) namely: • "Publish public consultation covering all key aspects of proposed new market access framework by end Q2, 2021/22 and Publish a consultation response with finalised policy positions by end Q4, 2021/22"; "Lay relevant SI by end Q1, 2022/23"; and "Publish key guidance documents by end Q3, 2022/23 with ongoing engagement with stakeholders over the course of 2022/23 to prepare them for the new framework." (Devices)	
PATIENT SAFETY	G/A
6. Deliver a more responsive safety surveillance and risk management system, for all medical products, to keep patients safe	G/A
11 deliverables – 9 Green, 2 Amber namely: • "Improve model of DEAC and its EAG by Q3, 2021/22, to ensure greater involvement of independent, scientific, technical, lay and clinical experts in regulatory decision making." (Devices) • "Agreed policy for a significantly enhanced transparency regime for medical device regulation by Q4, 2021/22; with key elements being delivered over 2022/23." (Devices)	
7. Deliver innovative interventions to ensure the UK has a secure supply chain providing high quality products	G/A
7 deliverables – 5 Green, 2 Amber namely: • "Roll out of automated inspection reports by Q4, 2021/22." (IE&S) • "Deliver a world-leading approach to inspections and enforcement with assurance that products are developed and manufactured to the highest standards and prompt action to reduce criminal threats throughout 2021/22 and 2022/23." (IE&S)	

DYNAMIC ORGANISATION	**G**
8. Deliver our Transformation Programme to make us a truly world-leading, innovative regulator	**G/A**
4 deliverables – 3 Green, 1 Amber namely: • "Deliver accompanying Transformation Programme and organisational redesign (staffing, governance, structures, processes) by Q4, 2021/22 and post implementation support including benefits realisation from April 2022 onwards." (Transformation Programme)	
9. Deliver a programme to enhance our leadership capability to attract, retain and develop talent so that we can fuel innovation and drive change	**G**
6 deliverables – 5 Green, 1 Blue	
COLLABORATIVE PARTNERS	**G**
10. Leverage international partnerships to drive better outcomes	**G**
8 deliverables – 7 Green, 1 Blue	
11. Leverage UK healthcare system partnerships to integrate processes and drive better outcomes	**G**
5 deliverables – 4 Green, 1 Blue	
12. Build public and stakeholder trust in our organisation through a programme of proactive and innovative communications	**G**
5 deliverables – 5 Green	
FINANCIAL SUSTAINABILITY	**G/A**
13. Establish a new business model for the future that increases income, reduces costs and improves productivity	**A**
5 deliverables – 3 Green, 2 Amber namely: • "Implement organisational design, creating a new, leaner structure for the organisation and balancing our costs by Q3, 2021/22." (Transformation Programme) • "Develop, consult on (Q3, 2021/22) and implement a new fee structure by Q2, 2022/23." (Finance / Policy)	
14. Deliver an optimised IT infrastructure to improve our service and reduce our costs with fewer digital technologies	**G**
5 deliverables – 5 Green	

Performance against delivery of items due in Q1

5. There were 7 items due for delivery in Q1. Of these, 2 were completed on time ("embed Delivery Plan in staff objectives"; "revise NICE Partnership Agreement"); 3 were delivered late by 1 month ("International Strategy"; "Culture Action Plan"; consultations for "legislative change"); 1 has been completed but voluntarily left as Green until the benefits can be realised after Lotus Notes software migration ("review devices signals and risk management process"); and 1 is on track for September (publish "Patient Involvement Strategy" – although most actions within the strategy are not being held up). The reason for these delays has been considered and the impact assessed as minor.

6. As this is the first quarter report, the focus has been on reviewing the action plans to address Amber items. More work is also planned on benefits realisation to enhance how we measure and demonstrate success and downstream benefits; this is being piloted as part of the transformation work and the IMMDSR response, and updates on these will come to the Board in due course. In the meantime, deliverables marked as complete will require sign off by the DPC and the ExCo, although they might be updated if the work evolves and requires ongoing monitoring.

Agreed action plans for Amber deliverables

7. The main focus of the Q1 reporting process has been to peer review and agree action plans for all Amber items to unlock barriers and avoid future delays (most are not due yet). The table below lists each Amber item along with a summary of the initial issue raised, discussions and actions taken during the reporting process and the ExCo's conclusion on next steps. During the review process, 3 items were brought back to Green/Blue (not shown below); 5 have had clear checkpoints identified (after which, if the action plan is successful, the items should be Green); and 8 remain Amber following an ExCo decision that the residual level of challenge still warrants continued monitoring.

8. Staff resourcing constraints given the current restrictions on recruitment and before the new organisational structure (ie size and shape programme) is implemented was a clear theme; on top of dealing with already challenging work. Teams have utilised project planning and reprioritisation of existing resource in the first instance (this brought three back to Green/Blue), and 5 areas have had exceptional approval for recruitment / use of reserves to mitigate the issue (***see items marked with * below***). This approval is dependent on a clear link to the Delivery Plan and a minimal risk that any new staff displace existing staff via implementation of the future operating model.

Summary of action plans for Amber deliverables

Deliverable	Summary of initial issue raised and actions being taken
Scientific innovation	
Deliver a set of work packages to ensure that **AI as a device is underpinned** by robust evidence to enable safer innovation by **Q4, 2022/23**. (Devices)*	**Reason for Amber:** progress has slowed due to a number of factors mainly the current recruitment freeze and the additional demands of dealing with COVID-19, Brexit, EU MDR implementation, and widespread safety/compliance issues in "software as a medical device" as these issues divert resources. **Action plan:** submit as an exceptional case for recruitment. Once the resource is in place, we should be able to bring this back to Green. It should remain Amber until then. We are still making good progress, mitigating impacts by shifting work from other projects and delaying work with external partners where possible. **ExCo decision: agreed item should stay Amber until extra resource in place and progress reviewed in Q2.**
Healthcare access	
Put in place new legislation this year to ensure safe access to innovative products and to protect public health: timings agreed and public consultations begin from **Q1, 2021/22** (Policy)*	**Reason for Amber:** Pressures on resources in policy and across wider teams has meant that public consultations planned to launch in June slipped. Timeframes are tight given current resources, but work is progressing. There is currently no economist support in the Agency. **Action plan:** we have prioritised this work and consultations for Point of Care manufacturing and EAMS have been launched in July, a month late. Consultation on changes relating to valproate are awaiting ministerial clearance, but write-round clearance in underway and we expect to be able to publish in September. Legislative changes for CTs have been delayed due to the Minister asking for a rethink, a submission was sent and is awaiting feedback. We have now secured approval to use reserves for economics resource; once in place, we should be able to bring this back to Green but propose to leave it Amber until then. **ExCo decision: agreed item should stay Amber until extra resource in place and progress reviewed in Q2.**
Resolution of any live **regulatory issues following EU transition** by **Q1, 2022/23** (Policy)*	**Reason for Amber:** the team continue to work with DHSC and OLS to resolve regulatory issues but resourcing issues, a high level of risk, challenge and links to wider dependencies make timely delivery challenging. **Action plan:** propose to remain on Amber given the level of challenge, plans were discussed in DPC and the ExCo. A virtual MHRA/DHSC project team is sharing capacity. We have secured permission to recruit additional staff. We are managing increased workloads by providing staff overtime. A risk register has been created and linked to the corporate risk register. **ExCo decision: agreed item should stay Amber given level of challenge, progress to be monitored.**
Publish public consultation covering all key aspects of proposed new market access framework by end **Q2, 2021/22** and publish a consultation response with finalised policy positions by end Q4, 2021/22; *and*	**Reason for Amber:** timetable is tight and we are dependent on external clearances to hit deadlines. Lack of analyst resource and pressures on legal capacity risks timescales for the consultation review and finalising the policy. We have had several resignations, increasing pressure to an already stretched team. **Action plan:** we propose this remains Amber as some risks to delivering on time are external factors and cannot be fully mitigated. However, we are making good progress and mitigating unexpected delays by pausing other work or bringing in support from other teams. The plan to secure economist resource is mentioned above. We will be putting in requests for positions to be agreed to support the immediate pressures. We are working closely with

Lay relevant SI by end **Q1, 2022/23*;** *and* **Publish key guidance doc** by end **Q3, 2022/23** with ongoing engagement with stakeholders over the course of 22/23 to prepare for the new framework. (Devices)	DHSC to ensure we have a clear path for clearance and cross-government review. Weekly meetings are being held with Government Legal Department to ensure we are being transparent with each other on the resource implications. **ExCo decision: agreed item should stay Amber given level of challenge, progress to be monitored.**
Patient safety	
Improve the model of the DEAC and its EAG by **Q3, 2021/22,** to ensure greater involvement of independent, scientific, technical, lay and clinical experts in regulatory decision making. (Devices)	**Reason for Amber:** preparatory work has been reliant on fast stream resource and they leave in September. The next phase will require resourcing to support more integrated working of DEAC (Devices Expert Advisory Committee) with Devices which mirrors more closely the approach with PEAG (Pharmacovigilance Expert Advisory Group). **Action plan:** work has been reprioritised so the team can focus on this with existing resources. The plan is to continue the current DEAC until June 2022, to submit a proposal on a 'shadow/pilot' statutory DEAC as an options paper to DEAC on 16 September and to have recruitment arrangements ready by the end Q3. Recruitment will commence Q4. Assuming all goes well at DEAC we should be on track to deliver this on time but we propose to keep it Amber in the meantime. **ExCo decision: agreed the item should stay Amber and RAG rating reviewed post Sept DEAC meeting, progress to be reviewed in Q2.**
Agreed policy for a **significantly enhanced transparency regime** for medical device regulation by **Q4, 2021/22;** with key elements being delivered over 2022/23.(Devices)	**Reason for Amber:** progress is being made but some key improvements (e.g. Medical Device Registration) are required: the future Statutory Instruments to mandate both the capture and release of data and this also needs economist support (currently there is none); and TD3 deliver the relevant IT applications on time and with all the functionality to make the data publicly available. **Action Plan:** since the Amber return submitted to the DPC, it's been confirmed that the DDaT roadmap includes the underpinning IT applications to deliver the planned data capture and transparency on time and fully scoped – this was a critical dependency. Progress has also been made securing economist support for the SI (see above). We propose to keep this as Amber as it needs monitoring and to ensure adequate focus on delivery in this complex area (particularly given the impact of Size and Shape and reductions in planned IT delivery scope). **ExCo decision: agreed item should stay Amber given level of challenge, progress to be monitored.**
Roll out of **automated inspection reports** by **Q4, 2021/2.** (IE&S)	**Reason for Amber:** higher priority work and insufficient inspector resource in all GxP areas to provide technical input to the automation of the basic report template makes delivery within the timeframe difficult. **Action plan:** this is part of a combined project that includes (i) the pilot for pre-inspection checks to fast track new applications and (ii) the use of referral to consultants. Those higher priority activities remain on-track but the use of automated inspection reports is challenging. We are currently reviewing the scheduling and allocation of resource across these various projects and plan to discuss options with the ExCo. We propose that this remains Amber in the meantime. IT support is also a dependency, and we will be working to clarify whether this support can be provided within IES or require TD3 support, pending any changes as a result of size & shape

	ExCo decision: noted progress and agreed the item should stay Amber, progress to be reviewed in Q2.
Deliver a **world-leading approach to inspections** and enforcement with assurance that products are developed and manufactured to the highest standards and prompt action to reduce criminal threats **throughout 2021/22 and 2022/23.** (IES&)	**Reason for Amber:** delays with recruiting key staff due to recruitment freeze mean inspection programme is currently insufficiently resourced pending transformation through the size and shape programme. **Action plan:** there are a range of projects in progress to deliver this transformation however we will not be able to move this to Green until we have progressed via transformation to ensure a risk-proportionate enabling of the product lifecycle with optimised resources. The earliest we could potentially expect a move to Green would be end of Q4 21/22. **ExCo decision: agreed item should stay Amber and RAG rating reviewed post size and shape implementation, progress to be monitored.**
Dynamic organisation / Financial suitability	
Deliver accompanying **Transformation Programme** and organisational redesign (staffing, governance, structures, processes) by **Q4, 2021/22** and post implementation support including benefits realisation from April 2022 onwards; *and* **Implement organisational design**, creating a new, leaner structure for the organisation and balancing our costs by **Q3, 2021/22. (TP)**	**Reason for Amber:** the programme has developed at a rapid pace and has revised its deliverables and timelines since the time of the delivery plan was drafted, these deadlines are no longer accurate. **Action plan:** remedial action is already being taken and is being driven via the Programme Board and other governance bodies including the ExCo and the Board, who have regular involvement and are being kept aware of progress. **ExCo decision: agreed item should be left as described and as Amber with progress monitored, noted significant amount of work, project management and governance / reporting arrangements already in place to manage delivery of the programme.**
Develop, consult on (Q3, 2021/22) and **implement a new fee structure** by **Q2, 2022/23**. (Policy)*	**Reason for Amber:** insufficient resource but recruitment underway. Fees process runs to strict timings and if a candidate is not in post by the end of Q2, the team will struggle to find resource to deliver on time without impacting other priorities. **Acton plan:** initial recruitment was unsuccessful but DPC and ExCo approval was secured for using Agency reserves to pay for short-term consultancy support. This is given the importance of this work to long term financial sustainability. Team propose to leave this as Amber until staff resource is in place and progress is made. **ExCo decision: agreed item should stay Amber until extra resource in place and progress reviewed in Q2.**

Recommendation

9. The ExCo has concluded that despite the challenges facing the Agency, good progress is being made and the revised reporting process is helping keep delivery on track. Action plans for Amber items have been agreed. Resourcing is a particular problem and 5 items have been granted approval for their Senior Responsible Owner (SRO) to apply for recruitment - provided they demonstrate a clear link to the Delivery plan and a minimal risk of displacing staff. Ongoing performance monitoring will be important given the staffing impacts of organisational redesign and the anticipated pressures over winter.

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

Jon Fundrey
21 September 2021

ANNEX – RAG STATUS OF ALL DELIVERY PLAN DELIVERABLES

This table shows deliverables with a RAG status reflecting confidence in delivery. The items that have been delivered are shown as Blue. Items showing slippage past their delivery date are shown in the "Due date" column. ***Items that were flagged in the published Delivery Plan as having particular patient benefit are asterisked in the number column.***

#	Delivery Plan Deliverable	Due date	RAG
SCIENTIFIC INNOVATION; 2. Deliver public health impact, world-leading research innovation and a unique proposition			
1	Risk-based approach to batch release: guidelines drafted by **Q3, 2021/22** and begin implementation of approaches via pilot studies from Q4, 2021/22.	Q3, 2021/22	G
2	Develop and publish our laboratory strategy and long-term plan, including a standards sub-strategy, by **Q4 2021/22**; and implemented from Q1 2022/23.	Q4, 2021/22	G
3	Upgrade our observational research infrastructure to enable timely and secure delivery of research data services: map out requirements by **Q4, 2021/22** and commence implementation of new systems by Q2, 2022/23.	Q4, 2021/22	G
4	Scale up two pilot primary care common data models to facilitate pharmacovigilance across different data sources: the Observational Medical Outcomes Partnership model by **Q1, 2022/23**; the 'Sentinel' model by **Q2, 2022/2023**.	Q1 / Q2, 2022/23	G
SCIENTIFIC INNOVATION; 3. Overhaul clinical trials system to support innovation and reduce time to approval			
5	Deliver two NIHR funded, real world pragmatic clinical trials through our innovative data-enabled clinical trials platform, with the first patients randomised in both trials by **Q3, 2021/20/22**.	Q3, 2021/22	G
6	Encourage a more innovative and pragmatic approach to UK clinical trials via an initiative to facilitate the uptake of novel trial designs and a communication effort to tackle the misperceptions that "traditional" clinical trials are always required for a licence by **Q4, 2021/22.**	Q4, 2021/22	G
7	a. Launch a new service that assists in the rapid recruitment of patients into commercial clinical trials, with the first contract in place by **Q3, 2021/22** and offer this service to companies as standard by Q2, 2022/23	Q3, 2021/22	G
7	b. and by **Q4, 2021/22** achieve 1 in every 4 UK GP practices signed-up to our clinical practice research data service.	Q4, 2021/22	G
8	Consult on options for changing UK legislation to make conduct of trials generating real-world data easier by **Q4, 2021/22**.	Q4, 2021/22	G
9	Publish guidance on points to consider when using trial designs with a real-world data element to support a licence application by **Q4, 2021/22**.	Q4, 2021/22	G
10*	Develop use of PROM via involvement in the "Setting International Standards in Analysing Patient-Reported Outcomes and Quality of Life Endpoints Data" international initiative from Q1 to **Q4, 2021/22**; and work up deliverables in 2022/23.	Q4, 2021/22	G
11	Deliver NHSX funded synthetic data research project by **Q4, 2021/22** and launch prototype synthetic data generation service by Q2, 2022/23	Q4, 2021/22	G
12	Finalise and promote the ILAP Novel Trial Design Tool in partnership with the wider health ecosystem by **Q2, 2022/23**.	Q2, 2022/23	G
13	Deliver a set of work packages to ensure that AI as a medical device is underpinned by robust evidence to enable safer innovation by **Q4, 2022/23**.	Q4, 2022/23	A

HEALTHCARE ACCESS; 4. Develop and deliver future strategy and approach for access to medicines and devices			
14*	a. Put in place new legislation [this year] to ensure safe access to innovative products and to protect public health: timings agreed and public consultations begin from **Q1, 2021/22**; *(There have been some delays launching consultations due to resource pressures but progress is still being made. Consultations for Point of Care manufacturing and EAMS have been launched. Consultation on changes relating to valproate are awaiting ministerial clearance over recess, but write-round clearance in now underway and we expect to be able to publish the consultation in Sept. Legislative changes for CTs have been delayed due to the Minister asking for a rethink, a submission was sent in response and is awaiting feedback.)* *N.B. the details of this deliverable will be updated once consultations are complete so monitoring can continue on the next steps for legislative change.*	Q1, 2021/22 **Slipped from June to July**	A
14	b. consult on a national scheme to replace the FMD's safety features regulation by **Q4, 2021/22;**	Q4, 2021/22	G
14	c. formulation of final post-standstill policy during **2022**;	2022	G
14	d. resolution of any live regulatory issues following EU transition by **Q1, 2022/23**.	Q1, 2022/23	A
15	a. Integrate with the HRA and NIHR Clinical Research Network to provide a fast track approval for defined clinical trials - criteria for approval agreed by end **Q2, 2021/22;**	Q2, 2021/22	G
15	b. 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
16	Reduce regulatory burden by working with stakeholders to identify which flexibilities introduced in response to COVID-19 are safe to embed by **Q3, 2021/22**.	Q3, 2021/22	G
17	a. Support access to generics and biosimilars via more global harmonisation in approval standards; seek membership of IPRP from **Q3, 2021/22**;	Q3, 2021/22	G
17	b. and take forward discussion of UK Biosimilar guidance in the Access Consortium from **Q3, 2021/22**.	Q3, 2021/22	G
18	Develop a mechanism to pilot joint clinical trial approval and clinical trial and licensing scientific and compliance advice via Access Consortium by **Q4, 2021/22**.	Q4, 2021/22	G
19*	Further develop the ILAP concepts and tools, in collaboration with the NICE and the SMC to create a world-class first port of call for medicines development and access by **Q3, 2021/22**.	Q3, 2021/22	G
20	Ensure integrated UK regulatory pathways for products that combine medicinal products and medical devices; consultation by **Q3, 2022/23**.	Q3, 2022/23	G
21	Continued regulation of NI, under the EU regulatory system, working closely with NIE to ensure continued access to life sciences products.	Ongoing	G
HEALTHCARE ACCESS; 5. Establish a new devices legislative framework to support safe innovation and ongoing access to products			
22*	Publish public consultation covering all key aspects of proposed new market access framework by end **Q2, 2021/22** and Publish a consultation response with finalised policy positions by end Q4, 2021/22.	Q2, 2021/22	A

23*	Lay relevant SI by end **Q1, 2022/23**.	Q1, 2022/23	A
24*	Publish key guidance documents by end **Q3, 2022/23** with ongoing engagement with stakeholders over the course of 22/23 to prepare them for the new framework.	Q3, 2022/23	A
PATIENT SAFETY; 6. Deliver a more responsive safety surveillance and risk management system, for all medical products, to keep patients safe			
25*	Complete review on new medical devices signals and risk management process, embed risk assessment template and identify opportunities for patient involvement by end **Q1, 2021/22.** *[The review is complete but we cannot implement until we migrate away from Lotus Notes so we are leaving it on here for now]*	Q1, 2021/22	G
26*	a. Further action on valproate to drive compliance with the PPP. Enhance the valproate registry by extending the established England registry to include all antiepileptics by end of **Q2, 2021/22;**	Q2, 2021/22	G
26*	b. and make available a UK-wide digital annual risk acknowledgment form alongside defining the extension of the registry to the whole of the UK by end of **Q4, 2021/22.**	Q4, 2021/22	G
26*	Improve model of DEAC and its EAG by **Q3, 2021/22,** to ensure greater involvement of independent, scientific, technical, lay and clinical experts in regulatory decision making.	Q3, 2021/22	A
27	Deliver an options appraisal for our project to investigate the role of genetics in the development of adverse drug and vaccine reactions by **Q3, 2021/22**	Q3, 2021/22	G
28*	a. Review of teratogen use during pregnancy, and consideration of the strategies of other regulators by **Q3, 2021/22;**	Q3, 2021/22	G
28*	b. with independent patient and stakeholder input and expert advice by **Q4, 2021/22**;	Q4, 2021/22	G
28*	c. and, if required, updated action and guidance by **Q2, 2022/23.**	Q2, 2022/23	G
29*	a. Deliver enhanced signal detection process by **Q4, 2021/22**	Q4, 2021/22	G
29*	b. service enhancement and international opportunities to defined in **Q4, 2021/22**; c. and delivered in 2022/23.	Q4, 2021/22	G
30*	Agreed policy for a significantly enhanced transparency regime for medical device regulation by **Q4, 2021/22;** with key elements being delivered over 2022/23.	Q4, 2021/22	A
PATIENT SAFETY; 7. Deliver innovative interventions to ensure the UK has a secure supply chain providing high quality products			
31	a. Pilot voluntary 'pre-inspection' checks to fast track new applications for manufacturing licences and piloting the use of consultants as 'compliance monitors' in remediation cases by **Q3, 2021/22**;	Q3, 2021/22	G
31	b. Roll out of automated inspection reports by **Q4, 2021/22**;	Q4, 2021/22	A
31	c. Identify new risk-proportionate approaches with our international partners by **Q4, 2021/22**;	Q4, 2021/22	G
31	d. Embed file-sharing platforms for remote inspections and visual technology capabilities as a standard part of inspections by **Q3, 2022/23.**	Q3, 2022/23	G

32	Deliver the GB Medicines Verification System, to replace the EU system and enable medicines to be tracked through the supply chain – delivery in partnership with the DHSC and to their **timescales when finalised**.	Tbc	G
33*	Deliver a world-leading approach to **inspections** and enforcement with assurance that products are developed and manufactured to the highest standards and prompt action to reduce criminal threats **throughout 2021/22 and 2022/23.**	Ongoing	A
34*	Deliver a world-leading approach to inspections and **enforcement** with assurance that products are developed and manufactured to the highest standards and prompt action to reduce criminal threats **throughout 2021/22 and 2022/23.**	Ongoing	G
DYNAMIC ORGANISATION; 8. Deliver our Transformation Programme to make us a truly world-leading, innovative regulator			
35	a. Embed Delivery Plan in staff objectives by **Q1, 2021/22;** *(The Delivery Plan was cascaded to all staff along with links to guidance in April in time for staff goal setting; a reminder was sent following ministerial approval.)*	Q1, 2021/22	B
35	b. monitor performance from **Q2, 2021/22** with an updated reporting approach;	Q2, 2021/22	G
35	c. and review and revise plan with the Department of Health and Social Care by **Q1, 2022/23** as part of annual business planning.	Q1, 2022/23	G
36	Deliver accompanying Transformation Programme and organisational redesign (staffing, governance, structures, processes) by **Q4, 2021/22** and post implementation support including benefits realisation from April 2022.	Q4, 2021/22	A
DYNAMIC ORGANISATION; 9. Deliver a programme to enhance our leadership capability to attract, retain and develop talent so that we can fuel innovation and drive change			
37	a. Develop an organisational culture action plan by Q1, 2021/22; *(The Board agreed the strategic culture priorities in July and the culture action plan is built around these. The plan is dynamic and will be kept under review and updated.)*	Q1, 2021/22 **Slipped from June to July**	B
37	b. and deliver associated actions; refresh plan in **Q1, 2022/23.**	Q1, 2022/23	G
38	Launch staff leadership action plan by **Q2, 2021/22**.	Q2, 2021/22	G
39	Deliver HR support and guidance to staff during organisational restructuring **throughout Q1-Q4, 2021/22**.	Q1-4, 2021/22	G
40	a. Identify future workforce and talent needs and deliver action to ensure we embed workforce planning by **Q2, 2021/22**;	Q2, 2021/22	G
40	b. and review workforce in **Q1, 2022/23** to identify follow up actions.	Q1, 2022/23	G
COLLABORATIVE PARTNERS; 10. Leverage international partnerships to drive better outcomes			
41	Development of an international strategy underpinning and aligned to the wider objectives in the Delivery Plan by **Q1, 2021/22.** *(The International Strategy was agreed by the Agency Board in July.)*	Q1, 2021/22 **Slipped from June to July**	B

42	Continuing our collaboration with the EU, through the establishment of the Medicinal Products Working Group, established under the Trade and Cooperation Agreement as a forum for bilateral cooperation that can be built on in future. **Q2, 2021/22.**	Q2, 2021/22	G
43	a. Full assessment of the linkages needed with the WHO, including in the context of our biological and control standards work by **Q2, 2021/22**;	Q2, 2021/22	G
43	b. Improve our ability to capture and exchange data with partners by adopting international standards including "Identification of Medicinal Products" regulations by **Q2, 2022/23.**	Q2, 2022/23	G
44	Establish greater international regulatory collaboration and alignment with the Access Consortium so patients benefit from timely access to high quality, safe and effective medicines from **Q3 2021/22.**	Q3 2021/22	G
45	Deliver a refreshed inspection network that adds strengths and international standing to the work of our inspectorate by **Q4, 2021/22.**	Q4, 2021/22	G
46	Collaborating with other country regulators to provide quicker access to the next generation of cutting-edge treatments, while maintaining the highest safety standards by **Q4, 2022/23.**	Q4, 2022/23	G
47	Actively engage in ongoing trade negotiations (with the USA, Australia, New Zealand and others), putting forward a positive regulatory agenda and enhancing areas of regulatory cooperation **throughout 2021-23** as per the DIT timescales	Ongoing	G
COLLABORATIVE PARTNERS; 11. Leverage UK healthcare system partnerships to integrate processes and drive better outcomes			
48	Agree a revised Partnership Agreement and a detailed package of work programmes with the NICE, focused on safety and standards, improving timely access to medicines and healthcare products for patients, and the promotion of innovation and growth by **Q1, 2021/22.** *(The revised partnership agreement has been completed and signed off by the ExCo. Underpinning work streams are underway and will be kept under review by the MHRA / NICE core strategic group.)*	Q1, 2021/22	B
49	Deliver our data sharing strategy across the health sector, underpinned with robust security standards and privacy by design by **Q3, 2021/22.**	Q3, 2021/22	G
50	Map and identify the most important partnerships for delivery of our 2021-23 objectives and refresh strategic relationships with detailed work programmes developed to maximise reach and impact across the system from Q2 and in place by **Q4, 2021/22.**	Q4, 2021/22	G
51	Continue delivery of our commitments to the DHSC and ministers **throughout 21-23.**	Ongoing	G
52	Run partnerships meetings with the DAs and wider stakeholder groups to inform and involve them about the delivery of their priorities, quarterly **throughout 21-23.**	Ongoing	G
COLLABORATIVE PARTNERS; 12. Build public and stakeholder trust in our organisation through a programme of proactive and innovative communications			
53*	Publish our Public Engagement and Involvement Strategy, which sets out how we can best include patients in our work by **Q1, 2021/22.** *(There has been a delay from the impact of the local election purdah and because of resourcing pressures. However, consultation responses and actions for the strategy were considered by PSEC in August and we have approval to publish in September.*	Q1, 2021/22 **Slipped from June to Sept**	G

	Nb this item was rated Green as the impact of the delay is minor. It is not holding up most of the wider patient involvement work, only the publishing date.)		
54	Develop and deliver further communications to support the evolution of our COVID-19 vaccines strategy from **Q2, 2021/22.**	Q2, 2021/22	G
55*	Enhance our Customer Service Centre to support effective engagement with patients and customers, enabling them to access the information they need when they need it from **Q4, 2021/22.**	Q4, 2021/22	G
56*	Develop and deliver communications to support the launch of new and ongoing activities (products, services, campaigns and issues) **throughout 2021/22 and 2022/23** (covers all communication deliverables in the plan).	Ongoing	G
57*	Issue ongoing, prompt and responsive safety communications, including COVID-19, falsified medicines and medical devices, safer medicines and devices for women, drug safety issues, reclassifications, product alerts and notifications; deliver communications to improve the understanding of and engagement with current and new medicine and medical device safety reporting services among patients and healthcare professionals, **throughout 2021/22 and 2022/23.**	Ongoing	G
FINANCIAL SUSTAINABILITY; 13. Establish a new business model for the future that increases income, reduces costs and improves productivity			
58	Implement organisational design, creating a new, leaner structure for the organisation and balancing our costs by **Q3, 2021/22.**	Q3, 2021/22	A
59	Use available cash reserves to fund necessary systems investments, operational deficits and restructuring costs until the end of our Trading Fund status at the end of **2021/22.**	End 2021/22	G
60	Develop, consult on (Q3, 2021/22) and implement a new fee structure by **Q2, 2022/23.**	Q2, 2022/23	A
61	Reduce corporate costs by 15% by the end of **2022/23.**	End 2022/23	G
62	Reduce non-pay costs of £60m by £6m per year through contract renegotiation and contract management by the end of **2022/23.**	End 2022/23	G
FINANCIAL SUSTAINABILITY; 14. Deliver an optimised IT infrastructure to improve our service and reduce our costs with fewer digital technologies			
63	a. Finalise our plan to overhaul costly legacy systems by **Q3, 2021/22** and start to deliver improved service and savings from Q4, 2021/22;	Q3, 2021/22	G
63	b. and to have a new regulatory management core system in place by **Q3, 2022/23**.	Q3, 2022/23	G
64*	Deliver a new digital self-service platform in beta by **Q4, 2021/22** and live in Q1, 2022/23 that will improve the service patients and customers receive.	Q4, 2021/22	G
65	Support the revised regulations around medical devices, deliver the digital self-service, automation and data platforms required by **Q3, 2022/23.**	Q3, 2022/23	G
66	Work with the HRA to deliver an enhanced clinical trials service by **Q4, 2022/23.**	Q4, 2022/23	G

Medicines & Healthcare products Regulatory Agency

BOARD MEETING HELD IN PUBLIC

21 September 2021

Title	What assurance can be provided by the Patient Safety and Engagement Committee (PSEC)?
Board Sponsor	Mercy Jeyasingham
Purpose of Paper	Assurance

What assurance can be provided by the Patient Safety and Engagement Committee (PSEC)?

1. Executive Summary

1.1 The fourth meeting of the Patient Safety and Engagement Committee (PSEC) reviewed the performance of the Customer Service Centre; reviewed final feedback on the Patient and Public Involvement Strategy; confirmed subjects and questions for future papers to the Committee; discussed plans to develop a reputational index; and reviewed proposals on involvement of stakeholders in the development of proposals on the Yellow Card Biobank. It also received feedback from the two Non-Executive Directors leaving the Committee.

1.2 The first joint meeting of PSEC and the Audit and Risk Assurance Committee was also held to discuss the regulation of Medical Devices.

2. Introduction

2.1 The fourth full meeting of PSEC was held on 6 August 2021 following the joint meeting with the Audit and Risk Assurance Committee (ARAC) on 24 June 2021.

3. PSEC discussed each of the following items at the meeting on 6 August:

3.1 **Customer Service Centre**

The Customer Service Centre (CSC) was launched on 23 March 2020. The Committee reviewed CSC's performance during its first 15 months of operation. Due to the COVID-19 pandemic and exit from the EU in 2021 volumes of enquiries rose to 72,000 during the first year of operation. This was against an expected volume of 44,000. Enquiry volumes are still high. The team adjusted its way of working to manage the call volumes. This included a matrix model of working; flexible hours to cover weekends and bank holidays; and contracting with the NHS Business Service Authority (NHS BSA). The Committee asked detailed questions on dealing with patients and the public including how calls are handled by NHS BSA, clarity on response times, missed calls and resolution rates. In reply to a question on dealing with distressed callers, PSEC noted that this was being dealt with through training with the patient engagement team on language and tone. The Committee were assured that the CSC had performed well during a time of immense pressure and had strategies for improving performance in the future. It was specifically pleased with the availability of data to demonstrate evidence on performance.

3.2 **Patient and Public Involvement Strategy Feedback**

The Patient Involvement strategy was approved by the Board in April 2021 when it was sent out for a final public consultation. Feedback covered four themes: "representative", "understanding", "partnership" and "realistic". The Committee were particularly interested in patient information leaflets which formed part of the feedback on understanding. Suggestions were made to look at this further. Representative issues covered renumeration and conflicts of interest. Renumeration needs to be investigated but so does ensuring diversity of input through thinking about expenses for carer support, different ways to attract

people who are not able to be free to attend during working hours, as well as other issues. Cross sector working and partnerships was a key area in the strategy. The Committee were keen to see the implementation of the strategy and the suggestions from the final consultation will be used to inform its implementation.

3.3 **Work Programme**

PSEC will meet twice more during 2021, so the proposed topics and questions for these meetings were discussed. A number of suggestions were made on the questions to be addressed on clinical trials and patient and public involvement. The Health Care Professionals Strategy; Complaint Handling; Medical Devices; the implementation of the patient and public involvement strategy; as well as updates on the Innovative Licensing & Access Pathway (ILAP) and the Yellow Card scheme all form part of the future work programme for the Committee.

3.4 **Reputation Index**

PSEC reviewed a proposal on Reputation Index, which forms part of the Balanced Scorecard reviewed by the Board. There is no standard way of measuring reputation, so the Agency is developing a bespoke approach. Reputation risk emerges when performance (or perceived performance) does not meet expectation. Failure of reputation can happen quickly or erode over time. The proposal covered different methods to measure reputation with different target audiences. The Committee wanted to make sure that diverse communities of interest were sampled and will receive further detailed information on this as the work progresses.

3.5 **Yellow Card Biobank**

PSEC was briefed on the scoping work that has started on the Yellow Card Biobank. This is the idea of capturing genetic information from patients experiencing adverse drug reactions. The scoping work had begun to involve healthcare professionals and patients and the public, but the numbers of people consulted were still quite small. PSEC made several suggestions on increasing the diversity and numbers reached in the scoping study which the team welcomed. A key part of engagement is to explain not only the benefits of the project but to explain how data is used and how it is safeguarded.

3.6 **Non-Executive Directors**

Two Non-Executive Directors (NEDs), Professor David Webb and Professor Bruce Campbell, were stepping down from the Committee as their appointments as Non-Executive Directors were ending. Both NEDs had been instrumental in establishing and shaping the Committee. The Chair welcomed their reflections and feedback on how the Committee could improve. Both the Chair and CEO also thanked them for their contribution.

4. Joint meeting with ARAC

4.1 The Patient Safety and Engagement Committee held a joint meeting with the Audit and Risk Assurance Committee (ARAC) on 24 June to discuss co-ordination of work and specifically Medical Devices. The Chair of ARAC gave brief verbal feedback on this meeting at the 20 July Board meeting but the Board did not receive a written report. The joint meeting had a detailed briefing on Medical Devices and discussed risks as well as the public consultation due to take place in the summer.

4.2 The Committees were confident that the Agency was prioritising a range of activities to enhance and strengthen the regulation of medical devices. How the various components of the new regulatory framework come together and are implemented as part of an integrated system should become clearer over the coming months. PSEC and ARAC plan to seek further assurance of this. The joint meeting had been useful to ensure that the Committees were able to co-ordinate their approaches to topics and was a more effective use of time for the Executive.

4.3 The next joint meeting of PSEC and ARAC will be held before the end of February 2022 to discuss SafetyConnect as well as an update on Medical Devices.

5. Conclusion

5.1 The Committee were assured on the performance of the Customer Service Centre. The final public consultation on the Patient and Public Involvement Strategy would inform its implementation. Subjects and questions for meetings up to the end of the year were agreed for the Committee's work programme. Further work was requested on diversity of input for both the Reputational Index and the Yellow Card Biobank as plans on this were being developed. Finally, the Committee thanked both Non-Executive Directors leaving the Agency for helping to establish PSEC and their input over the last year.

Mercy Jeyasingham
Chair Patient Safety and Engagement Committee
Non-Executive Director MHRA
September 2021