Medicines & Healthcare products Regulatory Agency

AGENDA FOR BOARD MEETING HELD IN PUBLIC

10:00 – 12:30 on Tuesday 16 November 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 Declarations of Interest?	Information	All
	3. What were the minutes &actions from last meeting?	Approval	Chair
	AGENCY PERFORMANCE		
10:15	4. What are the current issues from the CEO's point of view?	Context	June Raine
10:35	5. What is the performance of the MHRA on the Balanced Scorecard in Quarter 2?	Assurance	Jon Fundrey
10:55	6. What has the MHRA achieved compared to each Quarter 2 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
	HEALTHCARE ACCESS		
11:15	7. What has the Innovative Licencing and Access Pathway delivered and how will it be developed?	Strategic Direction	Marc Bailey
	DYNAMIC ORGANISATION		
11:35	8. What assurance can be provided by the Organisation Development & Remuneration Committee?	Assurance	Mandy Calvert
	FINANCIAL SUSTAINABILITY		
11:50	9. What assurance can be provided by the Audit & Risk Assurance Committee?	Assurance	Michael Whitehouse
	EXTERNAL PERSPECTIVE		
12:05	10. What questions do members of the public have for the MHRA Board?	Public Engagement	Chair
12:30	CLOSE OF MEETING	-	Chair

Medicines and Healthcare products Regulatory Agency

Minutes of the Board Meeting Held in Public of 19 October 2021

(10:00am – 12:30pm)

at the Academy of Medical Sciences, 41 Portland Place, London
and by Zoom Webinar

Present:

The Board

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

Others in attendance

Rachel Bosworth	Director of Communications *(via Zoom)*
Carly McGurry	Director of Governance
Natalie Richards	Head of the Executive Office
Jude Thompson	Executive Assistant to the Chair
Kathryn Glover	Deputy Director, Medicines Regulation and Prescribing, DHSC *(via Zoom)*

INTRODUCTION

Item 1: What are the priorities for this meeting, how will the meeting run and who are the new Board Directors?

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

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

1.3 The Chair welcomed the MHRA's new Non-Executive Director, Professor Graham Cooke, who has also been appointed as Deputy Chair of the MHRA Board.

Item 2: Are there any Apologies or Declarations of Interest

2.1 Apologies were received from Dr Sam Atkinson, Interim Chief Quality & Access Officer; John Quinn, Interim Chief Technology Officer; Greig Chalmers, Head of Chief Medical Officer's Policy Division at the Scottish Government; Alison Strath, Interim Chief Pharmaceutical Officer and Deputy Director at the Scottish Government, and Cathy Harrison, Chief Pharmaceutical Officer for Northern Ireland.

2.2 The Chair announced a change to his Declarations of Interests: the terms of his previous non-MHRA posts came to an end on 30 September 2021, and Mr Lightfoot will be taking on the role of Chair Designate for the NHS Sussex Integrated Care Board from 1st November 2021. The Board congratulated the Chair on this appointment.

2.3 Professor Graham Cooke announced his Declarations of Interest which will be published on GOV.UK for transparency.

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 In relation to action 53 regarding the Independent Medicines and Medical devices Safety Review (IMMDSR), the Board noted that following the last update to the Board in July 2021 on the short, medium and long term deliverables, the MHRA has been taking forward a piece of work to define how to measure the impact of these deliverables. The programme of work has three key themes – patient and public involvement, a responsive reporting system, and strengthened evidence of decision making. The Cumberlege Patient Reference Group has been vital in providing input. A benefits mapping exercise has been taking place where the key activities in response to the Cumberlege Review will be consolidated and mapped with indicators and metrics to track progress and identify longer term benefits. The Patient Safety and Engagement Committee (PSEC) will consider this at their next meeting.

3.3 In relation to action 56 regarding putting mitigations in place for new Non-Executive Directors' Declarations of Interest (DOIs), the Board noted that Governance Office has worked with the Chair to agree appropriate mitigations. The register of declared interests will be published on GOV.UK and any updates will be added upon declaration. This approach is being taken to ensure transparency and maximise public confidence in the operation of the MHRA Board.

3.4 Apologies were made to the observers of the September Board Meeting who encountered technical difficulties in watching the live stream. It was also confirmed that all members of the public who had submitted questions to the Board for that meeting had received a written response from the Chief Executive.

AGENCY PERFORMANCE

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

4.1 Dr June Raine presented the Chief Executive's monthly report, which covered topics within the four strategic priorities:

(i) Healthcare Access – including latest updates on the Innovative Licensing and Access Pathway (ILAP); new medicines approvals; COVID-19 vaccine booster doses; a consultation on the future regulation of medical devices in the UK; Point of Care manufacture and clinical trials regulation; COVID-19 tests and COVID-19 testing sample collection consumables; COVID-19 batch testing by NIBSC; FDA Project Orbis; the Access Consortium; an update on the Inspectorate's international activities; the British Pharmacopoeia and Lab Services; COVID-19 cross-system partnerships; COVID-19 international engagement; testing of cholera vaccines for the WHO stockpile; hosting of external students by NISBC; and the NIBSC contribution to a parliamentary report on vaccine technologies;

(ii) Patient Safety – including updates on COVID-19 vaccines safety monitoring; sodium valproate; topical steroids; Coroners' Regulation 28 letters for medical devices; medicines recalls; enforcement; an Assistive Technology workshop for patients and the public; Clinical Practice Research Datalink (CPRD) international users group meeting; and geographical representativeness of CPRD data;

(iii) Dynamic Organisation – including updates on the Transformation Programme; and the MHRA's first Patient Involvement Strategy; and

(iv) Financial Sustainability – including updates on the Spending Review (SR); finance projects; fees strategy; the British Pharmacopoeia; and a new grant awarded to NISBC for a gene therapy project.

4.2 The Board thanked Dr Raine for her report and provided comments. These included requesting assurance that the Agency has the resources and facilities to support staff through the transformation programme; ensuring that the new transformed Agency retains skilled staff to ensure resilience going forward; how the balanced scorecard can provide evidence the Agency is performing while the transformation is taking place; how medicines and devices safety information is published in the public domain and how the Agency keeps healthcare professionals and patients up to date when there is a safety concern. It was noted that the work on this latter point can be taken forward with the guidance of the Patient Safety & Engagement Committee (PSEC).

4.3 The Board provided further comments regarding new services which the Agency is developing and how these will be integrated into the transformation programme – it was noted the Organisational Development & Remuneration Committee (ODRC) will be able to provide advice in this area. Other comments included broadening the GP coverage of CPRD and the benefits of bringing the third GP system provider (TPP) onboard; developing close working relationships through the ACCESS Consortium and Project Orbis and the benefits of work-sharing initiatives; ensuring safe management of data and the upcoming Goldacre Report. The recent issue in relation to inaccurate COVID-19 laboratory test results, the accountabilities in this area and the need to ensure diagnostics are appropriately regulated was reinforced. The Agency's international strategy and the opportunities this will afford to UK patients with regards to early access was also highlighted. The Board thanked Dr Raine for her comprehensive report.

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 on how to manage the Spending Review (SR) and transition funding in the scorecard to ensure optimism bias is adjusted for and reforecasting is undertaken at appropriate points. Contingency planning in the event that the Agency does not receive any funding from the SR may also be required so that there is enough resource to undertake the required critical technology project work, noting the new Chief Technology Officer will shortly join the Agency.

5.2 The Board provided further comments regarding how to gain a better understanding of how competitive the UK is in the field of clinical trials – the Board advised that the data set for clinical trials should be updated to include international data to inform this measure. The Board noted the Agency is undertaking a comprehensive review of the clinical trials legal framework which will enable the UK to become more competitive in this field. Faster trial approval should be the desired outcome from this work.

5.3 The Board provided comments regarding the Agency's higher profile due to the COVID-19 pandemic and the increase in Yellow Card reporting rates which the Agency should strive to maintain; the timescales of generics licensing in in the UK in comparison to Europe; and examples such as the RECOVERY trial which demonstrated what can be done when the health system comes together. The Board agreed the Balanced Scorecard provides some assurance that the Agency is on track with the specific objectives, however further evolution of the measures will be required to enable a higher level of assurance.

Action 51 addendum: Continue to evolve the Balanced Scorecard metrics to include more outcome measures. Update the data set for Clinical Trials in the balanced scorecard. ***Jon Fundrey***

SCIENTIFIC INNOVATION

Item 6: How is the MHRA accelerating the approval and diversification of patient recruitment for clinical trials?

6.1 The Board considered a paper describing how the MHRA is accelerating the approval and diversification of patient recruitment for clinical trials to support the Government's initiative to make the UK one of the most attractive countries to develop new medical products. The Board were asked to comment on how the SPRINT service developed by CPRD to recruit patients to trials can be further developed; and any input from the Board as to where more can be done to provide guidance on patient recruitment and diversification in clinical trials and investigations.

6.2 The Board agreed that this is an exciting area for development and provided comments on how to address equity of access to clinical trials, for example how to recruit patients whose GPs are not signed up to CPRD; how increasing the scope and nature of CPRD will enable greater geographical reach; options to maintain diversification of representation, in particular in gender balance; and understanding the barriers which are limiting or deterring practitioners from signing up to CPRD and limiting or deterring patients from signing up or consenting to clinical trials.

6.3 The Board commented that more work could be done to reach out to patients to motivate and empower them to reach out to GPs; whether financial incentives should be utilised and whether other funding sources could be explored; and how to educate GPs and patients on the benefits of providing this data to CPRD.

6.4 The Board provided further comments regarding how to improve the quality of data gathering to inform real world data and generation of meaningful evidence; bolstering relationships with companies of all sizes (in particular small companies with limited resources) and providing support to improve their data gathering activities, noting this is an area that ILAP could help; and how to develop a public dashboard of metrics for trial recruitment, to help trial investigators identify locations to base their trials. The Board noted this is a key area for development to build the UK into one of the most attractive countries in the world for hosting clinical trials and developing new products.

Action 61: Prioritise the national and international initiatives to accelerate the diversification of patient recruitment for clinical trials, exploring options to maintain diversification of representation, in particular in gender balance. Consider development of a public dashboard of metrics for trial recruitment.

Marc Bailey

PATIENT SAFETY

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

7.1 The Board considered an assurance report from the PSEC, which had discussed scoping guidance on effective patient representation on committees and groups; the key priorities of the healthcare professionals' engagement strategy consultation; and assurances demonstrating how regulatory contribution and patient engagement are optimised for clinical trials in the UK. The Board noted that the Terms of Reference are currently being updated.

7.2 The Board provided comments regarding the SR bid and prioritisation of project spend, seeking assurance that spending on safety will be prioritised. It was noted that a joint meeting of PSEC and the Audit & Risk Assurance Committee (ARAC) is planned to address this. The PSEC will consider whether the new Safety Connect system is a truly responsive system for patients; and the ARAC will consider whether value is being delivered from driving this major piece of implementation and integration. The Board were content with the assurance provided from the PSEC.

CORPORATE GOVERNANCE

Item 8: What are the mitigations for the most important risks on the Corporate Risk Register (CRR)?

8.1 The Board considered a paper providing an overview of the main mitigations in relation to some of the key corporate risks, in particular on the risks relating to the Future Operating Model, patient engagement, trading fund status, and the IMMDSR actions; as well as an overview of all corporate risks.

8.2 The Board provided comments regarding the importance of maintaining regular conversations on risk. It was confirmed that the Corporate Risk Register will be reviewed every quarter by ARAC and every six months by the Board. The Board provided further suggestions to review the risk registers of other regulators as a comparison to ensure the MHRA is undertaking appropriate self-assessment; how to assess the cross-system risk across the whole health system in the UK; how much of an influence the MHRA has within the healthcare system in the current context; digital transformation; mitigations to account for potential funding gaps; ensuring integration and culture change is successful alongside the other components of the transformation; and international risks.

Action 62: Review the Corporate Risk Register to consider whether all strategic risks to Agency outcomes are accurately captured.

Carly McGurry

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. A large number of questions were submitted by members of the public and although most of them were answered, it was not possible to address every question in the available time. An action was taken to answer all of the remaining questions directly to the people who raised them.

Action 63: Send written responses to observers whose questions were not answered during the October Board Meeting. ***June Raine***

ANY OTHER BUSINESS

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

ACTIONS FROM MHRA BOARD MEETING IN PUBLIC – 19 OCTOBER 2021

The actions highlighted in red are due this month

Action Number	Action	Owner	Date	Status
Carried Forward from previous meetings				
29	Present an Agency Laboratory Strategy to the Board as part of the Agency Science Strategy.	Marc Bailey	~~21/09/21~~ ~~16/11/21~~ 15/03/22	
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. 21/09/21: Publish communication on GOV.UK on the MHRA work to develop a pathway for new genomic products	June Raine	~~18/05/21~~ ~~21/09/21~~ ~~19/10/21~~ 16/11/21	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 & 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~~ 18/01/22	
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.	Marc Bailey	~~19/10/21~~ 16/11/21	On Agenda
50	ARAC to review the Agency's financial performance in the first six months of 2021/22 21/09/21: Review spending of financial reserves at next ARAC	Michael Whitehouse	16/11/21	On Agenda
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~~ 16/11/21	On Agenda

	21/09/21: Review the outcome measures in the Balanced Scorecard and the RAG Ratings in the quarterly Delivery Plan reports before considering if the targets are ambitious enough. 19/10/21: Continue to evolve the Balanced Scorecard metrics to include more outcome measures. Update the data set for Clinical Trials in the balanced scorecard.			
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~~ 18/01/22	
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	
58	Update MHRA/DHSC Framework Agreement to coincide with the change in Trading Fund status.	Carly McGurry	31/03/22	
59	Board assurance committees to review their combined effectiveness and hold a board discussion on this topic.	Michael Whitehouse, Mercy Jeyasingham, & Mandy Calvert	15/03/22	
New Actions				
61	Prioritise the national and international initiatives to accelerate the diversification of patient recruitment for clinical trials, exploring options to maintain diversification of representation, in particular in gender balance. Consider development of a public dashboard of metrics for trial recruitment.	Marc Bailey	19/04/22	
62	Review the Corporate Risk Register to consider whether all strategic risks to Agency outcomes are accurately captured.	Carly McGurry	19/04/22	

63	Send written responses to observers whose questions were not answered during the October Board Meeting.	June Raine	16/11/21	Verbal Update

Medicines & Healthcare products Regulatory Agency

BOARD MEETING HELD IN PUBLIC

16 November 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
16 November 2021

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

'TOP 10' HEADLINES

- Following extensive engagement via workshops and meetings, supported by our 'Champions network', the staff consultation outcome on proposals for MHRA's transformation to 'One Agency – delivering for patients' has been under review.
- We authorised the first oral antiviral agent for treatment of COVID-19 infection, molnupiravir (Lagevrio), via our 'rolling review' process.
- The Isotretinoin Expert Working Group has met to discuss its recommendations following the call for information from patients and other stakeholders.
- There have now been 65 applications for innovative medicines under the Innovative Licensing and Access Pathway, and the All Wales Therapeutics and Toxicology Centre has joined the Steering Group.
- Together with FDA and Health Canada, we jointly published Good Machine Learning Practice for Medical Device Development, which includes development of AI as a medical device, the first time joint guiding principles had been developed.
- The new oral polio vaccine, nOPV2, developed by NIBSC to retain effectiveness against viral variants was endorsed by WHO SAGE to transition to wider use.
- NIBSC was redesignated as a WHO Collaborating Centre and International Laboratory for Biological Standards for another four years.
- A Task-and-Finish Working Group has completed review of a range of proposals to introduce new UK legislation on Clinical Trials in the first quarter of next year.
- Updated guidance was published on the requirements for licensing electronic cigarettes as medicines to support smoking cessation.
- The GMP Inspectorate has extended GMP certification for the Serum Institute India to include manufacturing and support facilities to support the regulatory submission of new COVID-19 vaccines, and vaccine availability globally.

HEALTHCARE ACCESS

COVID-19 antivirals

1. The MHRA approved the first antiviral medicine molnupiravir (Lagevrio), for treatment of mild to moderate COVID-19 infection in adults with a positive SARS-COV-2 diagnostic test and at least one risk factor for developing severe illness (obesity, heart disease, diabetes or older age (over 60)). The rolling review approach was used in order to reach a regulatory decision on benefit risk in the shortest time possible. The Commission on Human Medicines recommended grant of a conditional marketing authorisation and that a pregnancy registry should be established.

Innovative Licensing and Access Pathway

2. In the last month, we have received a further three applications for the Innovation Passport designation covering both common and rare diseases. There has now been a total of 65 applications for Innovation Passports. Additionally, we have received a further two requests for a Target Development Profile. From 4 October, the All Wales Therapeutics and Toxicology Centre (AWTTC) joined the established ILAP partners activities, including considering the criteria for an Innovation Passport.

Clinical Trials legislation

3. A short-life Task and Finish Group comprising a range of stakeholders including patient groups, research and NHS organisations and industry has reviewed and consolidated a range of proposals to remove obstacles and streamline the regulation of clinical trials, paying particular attention to topics that can be best addressed in guidance rather than legislation. The proposals will form the basis of public consultation on revised UK clinical trials legislation. Work to strengthen international co-operation on clinical trials is commencing in a Working Group on the International Coalition of Medicines Regulatory Authorities.

Medicines approvals

4. The Commission on Human Medicines (CHM) advised on several novel medicines and new indications including those for the treatment of respiratory and oncology conditions. Recognising the importance to the NHS of timely availability of generic medicines, an internal review of approval timeframes is under way with the aim of introducing risk-proportionate efficiencies.

COVID-19 vaccines

5. Rolling submission of data for several new COVID-19 vaccines has continued and the MHRA has had discussions with companies concerning the data requirements for new variant vaccines. The use of immunological bridging data for the approval of COVID-19 vaccines has also been discussed with companies and with international regulatory authorities. By the end of October 2021, NIBSC has tested and certificated 157 batches of Pfizer/BioNTech (55), AstraZeneca (74) and Moderna (28) COVID-19 vaccines, the equivalent of over 152 million doses available to UK and overseas vaccination programmes.

6. The good manufacturing practice (GMP) certificate for Serum Institute India has been extended to include manufacturing and support facilities to support the regulatory submission of new COVID-19 vaccines, using a pragmatic remote inspection based on the detailed onsite inspection performed in 2020. The MHRA GMP certification is a significant milestone for supporting regulatory submissions to regulators internationally and demonstrates how widely our assessments are being shared.

Validation for NHS testing of SARS-CoV-2 infection

7. The production of LAMP (loop-mediated isothermal amplification) validation panels by NIBSC has played a crucial role in the NHS Test and Trace programme. This PCR-like diagnostic assay is quick and convenient for Point of Care Testing but not as sensitive as PCR. As a result, NIBSC has produced a panel of materials to verify the performance of new laboratories as they came on stream.

NIBSC polio vaccine nOPV2 recommended for wider use

8. On 11 October the WHO Strategic Advisory Group of Experts on Immunization (SAGE) confirmed its endorsement of transitioning the novel oral polio vaccine type 2 (nOPV2) from its initial use period to its wider use phase. This follows a meeting in which SAGE considered several factors, including an independent review of safety data by the WHO Global Advisory Committee on Vaccine Safety (GACVS), which confirmed no major safety concerns. NIBSC scientists were central to the design and development of nOPV2 and from this year are now playing a key role in the vaccine roll-out under Emergency Use Listing. The WHO GPEI (Global Polio Eradication Initiative) published a web story outlining the implications of SAGE's endorsement.

NIBSC redesignated as WHO Collaborating Centre for Biological Standards

9. The WHO has reconfirmed NIBSC in its role as a WHO Collaborating Centre and International Laboratory for Biological Standards for another four years. Dr Hans Kluge, Regional Director of WHO, expressed his appreciation for the valuable contribution made by NIBSC and looked forward to the continuing successful collaboration. The redesignation is dependent on NIBSC being able to deliver the agreed workplan for its continued production of WHO International Standards and will run to 2025 when a new application will be required.

WHO International Standards produced by NIBSC

10. At the WHO Expert Committee for Biological Standardisation (ECBS) in October, NIBSC scientists presented proposals for new and replacement International Standards. Nine were established including: *Mycobacterium tuberculosis* (H37Rv) DNA for nucleic acid amplification technology (NAT)-based assays; Varicella zoster virus DNA for NAT-based assays; *Anti-Lassa fever virus* immunoglobulin G, plus its corresponding reference panel; and *Anti-thyroid peroxidase antibodies* - all of which will be used for in-vitro diagnostics. Replacement Standards were established for: *Follicle-stimulating hormone* (human recombinant) for bioassay; *Von Willebrand factor* concentrate; and *Ferritin* (human recombinant), and *Diphtheria antitoxin equine*. In addition, NIBSC presented on production of the 2nd International Standard for SARS-COV-2 immunoglobulin and the Reference Panel for antibodies for variants of concern.

Electronic cigarettes as a licensed medicine: published guidance

11. Updated regulatory guidance was published on requirements for licensing electronic cigarettes as aids to support quitting smoking. This new guidance was widely publicised and has resulted in enquiries from manufacturers seeking further regulatory and scientific advice on meeting the data requirements on safety and effectiveness.

Consultation on UK legislation for medical devices

12. We held two webinars, aimed at supporting stakeholders to respond to the public consultation on the future regulation of medical devices, targeted at industry professionals and at patients and the public respectively. Both were well attended with 530 people having attended the industry-aimed webinar and 452 people having joined the webinar aimed at patients and the wider public. We have published recordings of the webinars. This important consultation will close on 25 November 2021 and work will begin on detailed consideration of what is expected to be a full set of responses with the aim of bringing in new UK legislation in a phased way up to 2024.

PARTNERSHIPS NATIONAL AND INTERNATIONAL

NICE and MHRA

13. On 19th October the first joint Board-to-Board meeting of MHRA and NICE discussed a range of topics of mutual importance including patient involvement, access to innovative products and use of real-world data. The outputs of these discussions will inform future work by MHRA and NICE to better co-ordinate decision-making and improve timely patient and healthcare access to medicines and MedTech.

Access Consortium

14. The Access Consortium (Australia, Canada, Singapore, Switzerland and UK) Heads of Agencies met to discuss specific actions required to fulfil the objectives agreed in the Strategic Plan 2021-2024 as well as working group progress. The Biosimilars and Generic Medicines Working Group continues to meet to discuss alignment of regulatory procedures between agencies. The COVID-19 Vaccines and Therapeutics Working Group of the Consortium has been developing a consensus statement on authorising new COVID-19 therapeutics. A new clinical trials group is discussing potential future collaboration, review and approvals of clinical trials conducted in more than one of the Access countries.

international engagement on COVID-19 diagnostic tests

15. The MHRA devices team engages regularly with international regulators including the US FDA. The team recently held a number of bi-lateral conversations on the use of Lateral Flow Tests for identifying positive COVID-19 cases in asymptomatic individuals. This included answering a number of questions from the FDA on the evaluation of these devices. The US has recently added to efforts to increase access to over the counter COVID-19 tests, including a National Institutes of Health (NIH) Independent Test Assessment Program (ITAP).

NIBSC international meetings and workshops

16. During October, NIBSC scientists participated in a number of key international meetings and workshops, aimed at engagement in cutting-edge areas of science:

- Brazil's Institute for Infectious Diseases and Global/National Health, discussing vaccines to control meningitis and hospital-acquired infections, and also AMR
- TRANSVAC2, a European vaccine research and development infrastructure project coordinated by the European Vaccine Initiative (EVI) and dedicated to accelerating the development of safe, effective and affordable vaccines,
- Asia-Pacific Economic Cooperation (APEC) online communication platform for COVID-19 vaccine testing harmonization and information exchange of batch release activity
- WHO BioHub System which aims to allow Member States to voluntarily share non-influenza biological materials with epidemic or pandemic potential (BMEPP) to facilitate effective characterization and surveillance, plus timely production and equitable allocation of diagnostics, devices, therapeutics and vaccines
- COVID-19 Vaccines Global Access (COVAX) hosted meeting on "interpreting SARS-CoV-2 immune assay data involving variants and the use of the WHO International Standard for anti-SARS-CoV-2 immunoglobulin"; and on "NIBSC standards for virus neutralisation assays" at the Joint European Centre for Disease Prevention and Control /WHO Euro 6th Vector Control Working Group meeting on SARS-COV-2 antigenic characterisation.

Partnership working on artificial intelligence and software as a medical device

17. There have been significant advances nationally and internationally on innovative regulatory approaches to artificial intelligence and software as a medical device.

    - The Agency's Software Group has jointly published with the FDA and Health Canada 'Good Machine Learning Practice for Medical Device Development: Guiding Principles'. This guidance identifies 10 guiding principles which lay the foundation for developing GMLP that addresses the unique nature of these products, thereby helping promote safe, effective, and high-quality Artificial Intelligence as a Medical Device (AIaMD). This is the first substantive output linked to the MHRA's Software and AI as a Medical Device Change Programme. and it is anticipated to cement our continued collaboration with FDA for the future.

    - The STANDING together (STANdards for Data Diversity INclusivity and Generalisability) project, led by the University of Birmingham, will develop standards for datasets underpinning AI systems, to ensure they are diverse, inclusive and can support development of AI systems which work across all demographic groups. The MHRA's Software Group will partner with the project, as it is envisaged that the findings will be useful in ensuring AIaMD takes account of the diverse populations in which these devices can be deployed.

    - The Devices Division contributed and will continue to contribute expertise to the development of QUADAS-AI (a quality assessment tool for artificial intelligence-centred diagnostic test accuracy studies). The initial announcement was published in Nature Medicine on 11 October. It is anticipated that guideline tools such as QUADAS-AI will advance the state of the art and contribute to more robust evidence bases for AIaMD.

Pharmaceutical Inspection Co-operation Scheme

18. We have secured Pharmaceutical Inspection Co-operation Scheme (PIC/S) board approval for the development of stand-alone expert circles for good clinical practice (GCP) and one for good pharmacovigilance practices (GVP). The MHRA chairs the current PIC/S working group on GCP and GVP which has centred on the Joint Visit Programmes to date. This is a significant development in terms of international collaboration and presents further opportunities for the MHRA to influence international harmonisation I relation to inspections.

PATIENT SAFETY

Safety of COVID-19 vaccines

19. As of 20 October, for the Pfizer/BioNTech, COVID-19 Vaccine AstraZeneca and COVID-19 Vaccine Moderna, the overall reporting rate of suspected adverse reactions is around 3 to 6 Yellow Cards per 1,000 doses administered. For all COVID-19 vaccines, the overwhelming majority of reports relate to injection-site reactions (sore arm for example) and generalised symptoms such as 'flu-like' illness, headache, chills, fatigue (tiredness), nausea (feeling sick), fever, dizziness, weakness, aching muscles, and rapid heartbeat. The nature of reported suspected side effects is broadly similar across age groups, although, as was seen in clinical trials and as is usually seen with other vaccines, they may be reported more frequently in younger adults.

Provision of safety information on sodium valproate

20. The DHSC has launched a consultation on original pack dispensing which includes MHRA proposals to introduce a requirement to ensure medicines that contain sodium valproate are always dispensed in the original manufacturer's packaging. The aims of the proposals behind enabling original pack dispensing and whole pack dispensing of medicines containing sodium valproate, are to support increased patient safety by ensuring patients receive the necessary information that is included in the original manufacturer's packaging about the safe and effective use of sodium valproate in women of childbearing potential.

Safety review of Isotretinoin

21. The Isotretinoin Expert Working Group (IEWG) met in October to agree their recommendations having considered the available information including information received from patients and other stakeholders. The IEWG has held eight meetings including three meetings where patients and other stakeholders presented their views which added to the material received through the public call for information. The Commission on Human Medicines will consider the recommendations of the IEWG at its next meeting. It is anticipated that patients and other stakeholders will continue to be involved in the implementation of agreed recommendations.

Safe use of tofacitinib

22. Treatment with tofacitinib, a medicine used in rheumatoid arthritis, psoriatic arthritis and ulcerative colitis, has been associated with an increased risk of heart attacks and certain cancers compared with the use of TNF-alpha-inhibitors. The incidence of these adverse events is low and has been linked to existing risk factors for these conditions such as older age or smoking. In light of the new evidence, the CHM has advised that tofacitinib should not be used in patients older than 65 years of age, people who are current or past smokers, or individuals with other cardiovascular (such as diabetes or coronary artery disease) or malignancy risk factors unless there are no suitable treatment alternatives.

Chloral hydrate and restriction of paediatric indication

23. Following a national review of safety and efficacy, the paediatric indication for chloral hydrate (for children aged 2 years and older) and chloral betaine (children aged 12 years and older) has been restricted to short-term treatment (maximum 2 weeks) of severe insomnia, only when the child or adolescent has a suspected or definite neurodevelopmental disorder and when the insomnia is interfering with normal daily life. Chloral hydrate and chloral betaine should only be used when other therapies (behavioural and pharmacological) have failed.

Safety of breast implants

24. On 22 October we met Poly Implant Prostheses (PIP) Action, a patient group campaigning on breast implant safety, to discuss their concerns regarding breast implant safety. On 1 November new webpages on Breast Implant Associated Anaplastic Large Cell Lymphoma (BIA-ALCL) were published on GOV.UK which aim to provide accurate information on this rare condition. The pages also outline the role of the Plastic, Reconstructive and Aesthetic Surgery Expert Advisory Group of the Devices Expert Advisory Committee (PRESEAG) in monitoring this condition and providing expert advice. Research to provide insights into patient and public perception of risk related to breast implants is being commissioned by MHRA.

Enforcement

25. Analysis carried out by the Enforcement Group which was subsequently shared with the Police has helped locate a site and seize products believed to be involved in illegal manufacturing of falsified medicines. The Financial Investigation Unit (FIU) continues to make effective use of Account Freezing Orders (AFO) to disrupt those suspected of involvement in medicines related crime. FIU activity has included obtaining AFOs on mule accounts used by an organised crime group to launder the proceeds of crime and also requests for the closure of accounts used to facilitate the illicit supply of Prescription Only Medicines and Controlled Drugs (CDs). Ongoing partnership with the Crown Prosecution Service resulted in dismissal of a defendant's appeal against a 6-year prison sentence and then the grant of a confiscation order of approximately £108,000 for charges relating to the supply of CDs. Another confiscation order was granted against the defendant in a separate trial to the value of £90,000.

DYNAMIC ORGANISATION

Transformation Programme

26. Following extensive engagement via a range of staff engagement opportunities including manager briefings, open group sessions for all staff, local teams and individual meetings, supported by our network of 'Champions', the outcome of a consultation with staff on formal proposals to transform the Agency has been intensively reviewed. Work to enhance the future organisational structure proposal on the basis of feedback from staff is progressing as appropriate and will be communicated to staff later in November. We are continuing to work with key stakeholders to finalise the integrated implementation plan and to implement the future operating model in alignment with the Agency delivery plan 2021 – 2023 and our strategic objective to deliver patient outcome centred services.

FINANCIAL SUSTAINABILITY

Spending Review

27. Whilst the overall outcome of the Spending Review has been announced, the Department of Health and Social Care has said that it will go through a robust business planning round before allocations for individual policies and arms-length bodies can be confirmed. We await details of that process and will engage fully to optimise resources for transformation, strengthened safety systems and innovation.

Financial forecast

28. We have updated the Agency's financial forecast until the end of the financial year in March 2022 and also the 'most likely outcome' forecast for the next three years which reflects the agency's new staffing profile and reduced operating costs. Both of these have been discussed by the Executive Committee and also reviewed by the Audit and Risk Assurance Committee. In order to maximise the use of the financial reserves before the end of the financial year as the Agency transitions from its status as a Trading Fund, the Resources Committee is meeting weekly to consider proposals for utilising the reserves that also deliver value for money.

June Raine CEO
November 2021

Medicines & Healthcare products Regulatory Agency

BOARD MEETING HELD IN PUBLIC

16 November 2021

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

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

1. Executive Summary

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

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

2. Introduction

2.1 This quarterly balanced scorecard for Quarter 2 (Q2) has been updated with data up to 30th September 2021.

3. Balanced Scorecard Development

3.1 Productivity model output has been included in the report for the first time. This metric examines the fee earning activity outputs for the regulator against the staff inputs for a given quarter to calculate our productivity vs the 20/21 Quarter 3 (Q3) and Quarter 4 (Q4) average.

3.2 Following feedback from the Board that some targets are not stretching enough, the Delivery and Performance Committee asked the balanced scorecard team to engage with Executive Committee (ExCo) members to review the targets. Engagement continues and the proposal is to complete this review in the new year under the new structure and ways of working. One exception to this was an agreement to review the corporate overhead % targets, which will involve maintaining the current budget target but adding a 'long term' ambition target of where we think we should be.

3.3 Assurance Committee chairs have also been engaged, with one meeting currently outstanding. One key suggestion to come from these meetings is to produce a coversheet explaining each metric. This will be produced for the next quarterly report.

3.4 Civil service culture survey scores have now been included with the key questions being monitored around 'Leaders Walking the Talk' and 'Taking Timely Decisions. We have also introduced inclusion metrics for the first time, these focus on % of our Grade 7 and above populations consisting of BAME and disabled staff. The people engagement score shown is now also the updated Q2 pulse survey result.

3.5 Other metrics that have now been updated with live data for the first time are grant % success rate, research papers published and device registrations

3.6 Reputational index metrics remain sample data. Discussions with suppliers are ongoing and the earliest these metrics will be available is Q4 after procurement and data collection has been completed.

4. Q2 Metrics Commentary

Patient & Public Involvement

4.1 Positive Media Sentiment

The MHRA featured in 1,602 articles in Q2, representing a slight increase of 8 percentage points quarter-on-quarter. COVID-19 continued to be the primary driver for coverage mentions, featuring in 88% of all items. The most prominent stories relating to COVID-19 in Q2 included discussion and eventual approval of Pfizer vaccinations for children and young people aged 12+, discussions of vaccine side effects such as myocarditis and pericarditis from the Pfizer/BioNTech vaccine, and coverage on booster vaccinations as the UK heads towards Winter 2021-2022 (MSN UK, Daily Mail, Daily Express Online).

Scientific Innovation

4.2 Clinical Trials

The total number of clinical trial applications increased by 33% from the previous quarter to 286 in Q2, which included 36 First in Human studies compared to a target of 20. The number of clinical trial applications is also growing when viewed on an annual basis as research activity recovers after EU exit and the impact of the COVID-19 pandemic last year. The research environment is still balancing COVID-19 and non-COVID-19 work. The Clinical Trials Unit is continuing to pro-actively support the use of novel trial designs, especially in early phase development, and has observed an increase in applications for complex trials and advanced therapies.

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Healthcare Access

4.3 Early Access to Medicines (EAMS)

Early Access to Medicines – Promising Innovative Medicine (EAMS PIM)
Steady uptake of this route with 4 PIM requests received this quarter and 7 granted.

Early Access to Medicines – Scientific Opinion (EAMS SO)
An increased number of applications for EAMS SO following previous positive PIM designation, with 4 applications received and 2 determined with positive opinions enabling patient access to treatment for unmet medical needs.

4.4 Paediatric Investigation Plan (PIPs)

Q2 2021 is the first quarter where PIP applications received on APPIAN is being reported and an increase has been seen in Q2 compared to the preliminary figures in Q1.

4.5 New Active Substances (NAS)

Overall, a decrease in the number of NAS applications received and granted compared to Q1 in which a spike was observed however the proportion of full national applications is considerably higher - at 50% - than in previous quarters. Determination of full national applications is expected to increase towards the last quarter as pending applications continue to progress through the relevant assessment stages and reach determination.

4.6 Innovative Licensing and Access Pathway (ILAP) Passport Applications

Interest in the pathway remains high with 23 applications received this quarter. 14 applications were determined with 86% concluding positively. With wider interest in the pathway now reflected in greater application volumes the percentage of positive outcomes has decreased slightly. This is not unexpected as it is anticipated that not all applications would fully meet the ILAP criteria. As expected, the earlier Innovation Passport applications are now progressing to the Target Development Profile (TDP) stage with 4 submitted this quarter.

4.7 Generics

A slight decrease in the total numbers of generic applications received and determined this quarter. Overall, the numbers remain higher than normal with year to date volumes for national applications exceeding last year's figures. Reliance route applications received and determined are higher than observed in Q1 but still account for only around 15% of applications.

4.8 Time to determination

The average net time to determination over the last three years indicates that the average time taken by the MHRA to process abridged applications continues to reduce with an average net time of 219 days in the first 9 months of 2021 compared to 222 days in 2020 and 230 days in 2019. A review of the gross time to determination indicates a similar positive trend with the **proportion of applications determined in less than 12 months increasing to 31% from January – September 2021** compared to 24% in 2020 and 21% in 2019.

Patient Safety

4.9 Adverse Drug Reactions and Signals

There has been a significant increase in Yellow Card reporting since December 2020 which saw the authorisation for use of COVID-19 vaccines. Numbers of reports have started to fall but are still significantly higher than numbers received before the pandemic and roll out of the COVID-19 vaccines, where around 3,000 to 4000 reports were received per month. The same is true for the volumes of signals which are more than triple the volumes received throughout 2020.

The September edition of Drug Safety Update was published with new information for healthcare professionals and patients on topical steroid withdrawal reactions. We also included articles to summarise advice on COVID-19 vaccines and medicines for September 2021 and 'Dear Health Care Professional' letters, medicine recalls and notices issued to healthcare professionals in August.

4.10 Device Registrations

Device registrations continue to perform well, enabling MHRA to build our understanding of devices in use to better protect patient safety. High volumes of applications represent a resource pressure but we are managing that by asking applicants to use different deadlines for different types of devices depending on risk. We are also using trained temporary staff to address the surge, working alongside more established staff to maintain standards

Dynamic Organisation

4.11 Number of Staff

The number of full time equivalent (FTE) staff only declined by 1.6% from the previous quarter to a total of 1,354 in Q2 due to resignations and restrictions on recruitment. Future targets will be based on the headcount of the transformed organisation.

4.12 Culture Survey

Culture figures are being introduced from this month and the baseline figures have been taken from a Civil Service wide survey undertaken in September 2021 to which 353 agency staff (ie about 30% of total) responded. Of the benchmarks available, “leaders walking the talk” and “taking timely decisions” have been selected and the Civil Service average benchmark is provided for comparison. The intention is to re-run the questions in our own Pulse Surveys on a quarterly basis and include this data on an ongoing basis.

4.13 Equality, Diversity and Inclusion

In April 2018, a Civil Service wide target was set in order to increase the recruitment of ethnic minority and disabled staff into the Senior Civil Service.

This data is regularly published by core departments who have internal targets too. Whilst we do not have an internal target yet, it is important to both monitor and hold ourselves accountable for our future talent pipeline.

4.14 Productivity

Productivity scores have been high since ADRs increased from around 8k per quarter to 179k in Q4 20/21. However, in Q2 we have seen this fall back to 76k as the COVID vaccination programme has slowed down which is contributing to a lower score. We have also seen a reduction of variations and national applications. These items have resulted in Q2 productivity scores of 80 for the Licensing division and 78 for the Vigilance & Risk Management of Medicines (VRMM) division. The Inspections, Enforcement & Standards (IES) division have a flat score of 104 as chargeable inspectorate days are actually down but this has been offset by increases in enforcement threat reduction outcomes. Meanwhile a high level of device registrations means the Devices division has a score of 115.

4.15 Engagement Score

People Engagement score was identified early on as one which we wished to report on and the baseline figure of 67.7% has been extracted from the 2020/21 Civil Service People Survey, for which we had a response rate of 70%. The figure of 57.7% relates to a re-run of the relevant questions in a Pulse Survey in Q2 of this year. The intention is to re-run these questions and thereby this engagement score in Pulse surveys and report quarterly.

Financial Sustainability

4.16 Cash Balance – Available Reserve

This metric now correctly shows the cash reserves, rather than the cash balance. The increase we saw in Q1 was expected due to service fee invoicing and we saw an expected decline in Q2, which we expect to continue as we use our reserves before transition into DHSC. Current projections result in a year-end cash reserve of £19.5m, even though we had previously communicated that we would use all of our cash reserves this year as any remaining reserves will be transferred to the Treasury due to the loss of our Trading Fund status. This variance is due to a change in planning assumptions and lower than expected project costs, especially in transformation. We had previously reserved £25m for transformation but are now forecasting that this will cost just £15.5m in 2021/22, with further costs anticipated next year if we can secure the funding.

4.17 Operational Surplus/Deficit

Operational surplus of £3.5m is £5.9m ahead of budget. This continues to be driven by lower than budgeted staff costs and information & communications technology (ICT) spending. Staff costs savings of £3.9m year to date align with the forecasted full year saving of £8.1m, although further reductions in staff could see this increase, whilst reduced ICT spend is expected to result in a year-end saving of £1.5m.

4.18 Non-Pay Savings

Non-pay savings relates to the project the Commercial Team are currently leading on to reduce non-pay costs via contract negotiations or removal of unnecessary costs. Currently no savings have been realised but opportunities have been identified that total £7m of savings versus a target of £6m.

4.19 Corporate Overhead %

Corporate overheads have increased from 29.4% in Q1 to 31.3% in Q2 but are still below what we had planned. The budget had corporate overheads of 31.7% and the current underspend is due to lower ICT spending to date but this is expected to increase in the second half of the year. By the end of the year we expect corporate spend to be at the 31.7% budgeted level, with the remaining ICT expenditure being offset by reduced travel and staff costs elsewhere in the agency.

5 Recommendation

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

Jon Fundrey
November 2021

Patient & Public Involvement

Public Communications Engagement (SAMPLE DATA ONLY)

145

KPI

Trend

Reputational Index (SAMPLE DATA ONLY)

+1

Target: 0

KPI

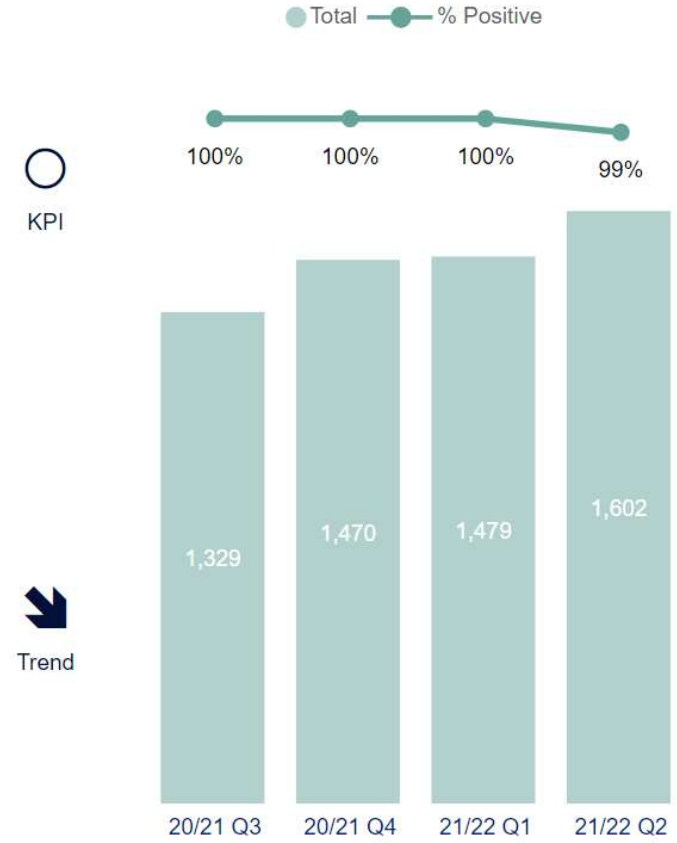
Trend

Positive Media Sentiment

99.0%

KPI

Trend



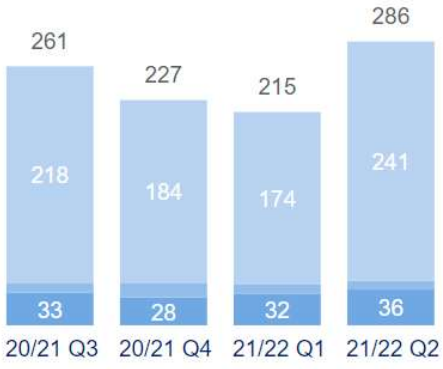
Scientific Innovation

Clinical Trials

Normal
241
Target: 184
KPI ▲ Trend ↗

Novel
9
Target: 10
KPI ▼ Trend ↘

FIH Approvals
36
Target: 20
KPI ▲ Trend ↗

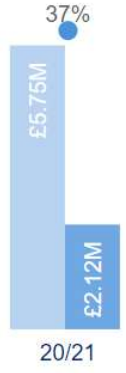


Grants % Success Rate

Grants Applied For
£5.75M
KPI ○ Trend →

Grants Received
£2.12M
KPI ○ Trend →

% Success
37%
Target: 37%
KPI ▶ Trend →

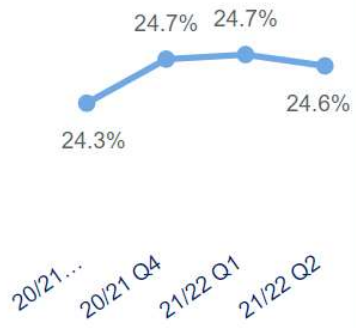


Research Papers Published

83
KPI ○
Trend →

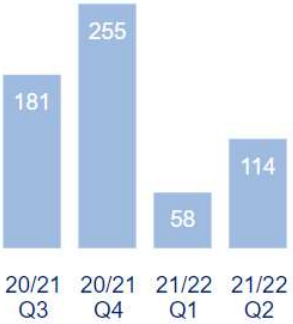
CPRD UK Population Coverage

24.6%
Target: 25.0%
KPI ▼
Trend ↗



Publications using CPRD Data - FinYTD

114
KPI ○
Trend ↘



Healthcare Access

EAMs - PIM-D Applications

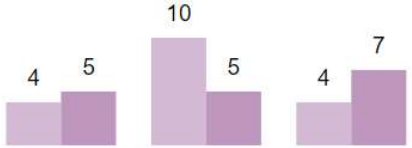
Received
4
Target: 6

Granted
7

% Positive
100%

KPI ▼ Trend →
KPI ○ Trend ↗
KPI ○ Trend →

100% 100% 100%



EAMs - EAMs SO Applications

Received
4
Target: 3

Granted
2

% Positive
100%

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

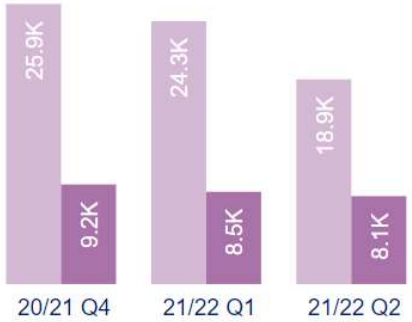
100% 100% 100%

Standards Sales Volume

NIBSC (Non Flu)
18,936

BP
8,133
Target: 8,700

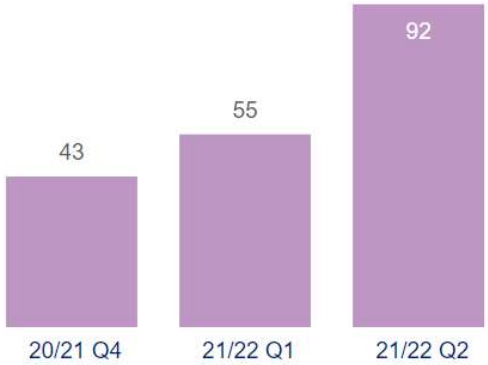
KPI ○ Trend ↘
KPI ▼ Trend ↘



PIPS Volume

92

KPI ○
Trend ↗



Healthcare Access

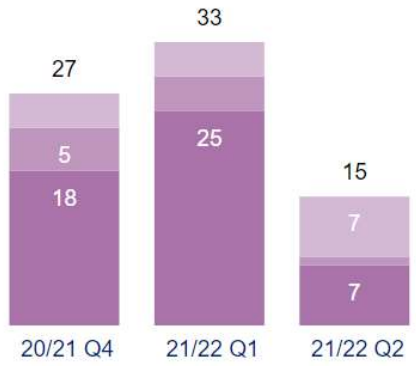
NAS - Applications Received

National (PL-GB/PL UK)
7

Orbis/Access
1

EC/MRDC Reliance
7

KPI Trend
KPI Trend
KPI Trend



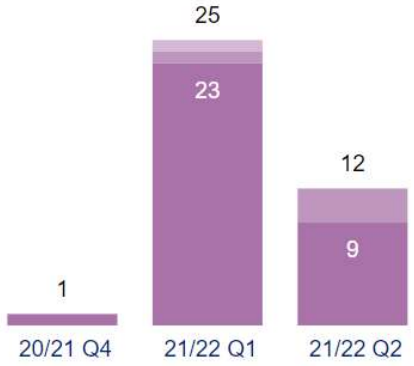
NAS - Applications Determined

National (PL-GB/PL UK)
0

Orbis/Access
3

EC/MRDC Reliance
9

KPI Trend
KPI Trend
KPI Trend



ILAP Passport Applications

Apps Received
23
Target: 10

Apps Determined
14

% Positive
86%

TDP Meeting Requests
4
Target: 5

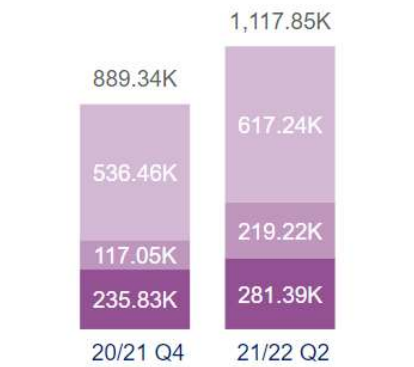
Device Registrations

Deadline 01/05/21
617,244

Deadline 01/09/21
219,216

Deadline 01/01/22
281,393

KPI Trend
KPI Trend
KPI Trend



Healthcare Access

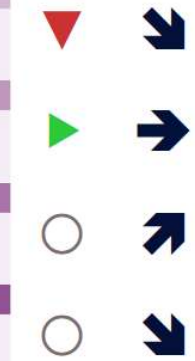
Variations - Applications Received

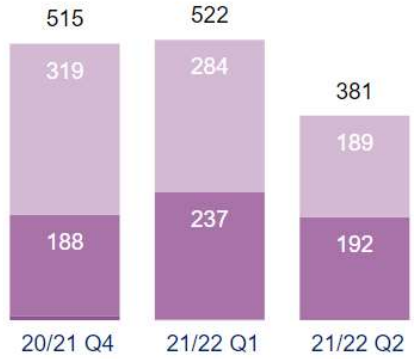
National (Std + Complex)
189
Target: 270

Type II Ext Complex
0
Target: 0

Type II ECDRP
192

Type II Orbis
0





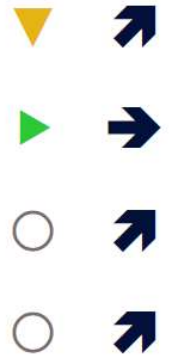
Variations - Applications Determined

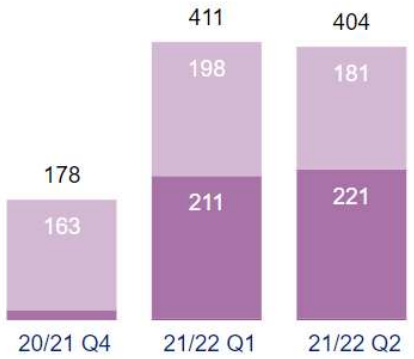
National (Std + Complex)
181
Target: 189

Type II Ext Complex
0
Target: 0

Type II ECDRP
221

Type II Orbis
2





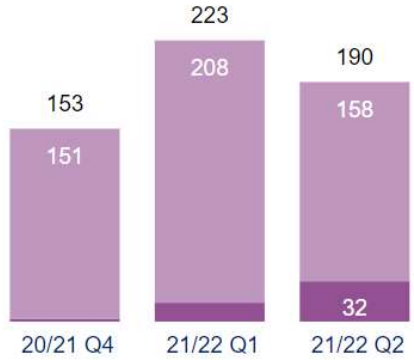
Generics - Applications Received

National MAs
158
Target: 168

KPI
Trend

EC/MRDC Reliance
32

KPI
Trend



Generics - Applications Determined

National MAs
92
Target: 57

KPI
Trend

EC/MRDC Reliance
16

KPI
Trend

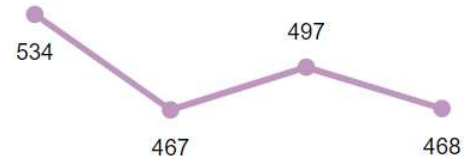
Healthcare Access

Abridged - Applications Received

Average Gross Time (Rec to Det Days)

468

KPI

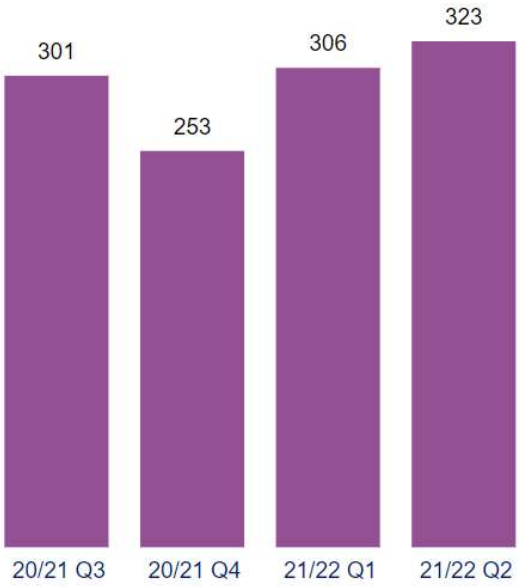


Trend

Number Received

323

KPI



Trend

Abridged - Applications Determined

Average Net Time (Clock On Days)

229

KPI

Trend

Number Determined

252

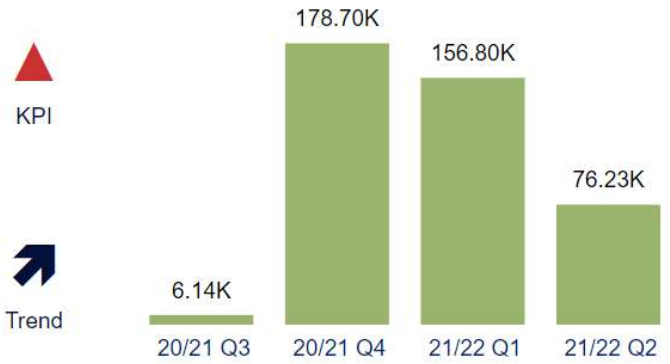
KPI

Trend

Patient Safety

Adverse Drug Reactions

76,225
20/21 Q2: 9,191 (+729.34%)



Devices - Adverse Incidents

8,112
20/21 Q2: 5,560 (+45.9%)

Adverse Blood Reactions

186
20/21 Q2: 209 (-11%)

Patient Safety Interventions

Major Signals
99,377
20/21 Q2: 26,830 (+270.4%)

Manuf Safety Comms
10
Target: 12

MHRA Safety Comms
10
Target: 3

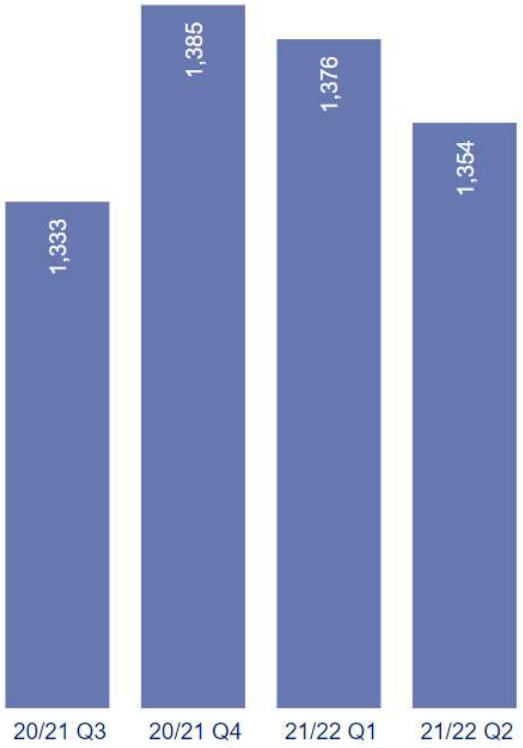
Dynamic Organisation

FTE

1,354
Budget: 1,458 (-7.13%)

KPI

Trend



CS Culture Survey - % Positive Response

Leaders "Walking the Talk"

13%
CS Benchmark: 39%

KPI Trend

Take Timely Decisions

29%
CS Benchmark: 39%

KPI Trend

Equality, Diversity and Inclusion

G7 and above - BAME Staff %

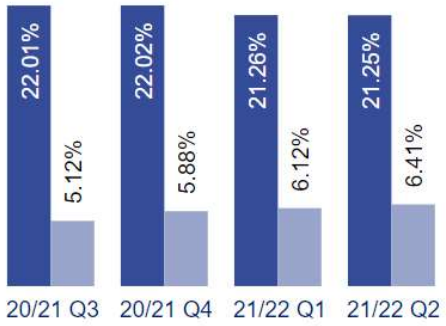
21.25%
CS Benchmark: 13.20%

KPI Trend

G7 and above - Disabled Staff %

6.41%
CS Benchmark: 12.80%

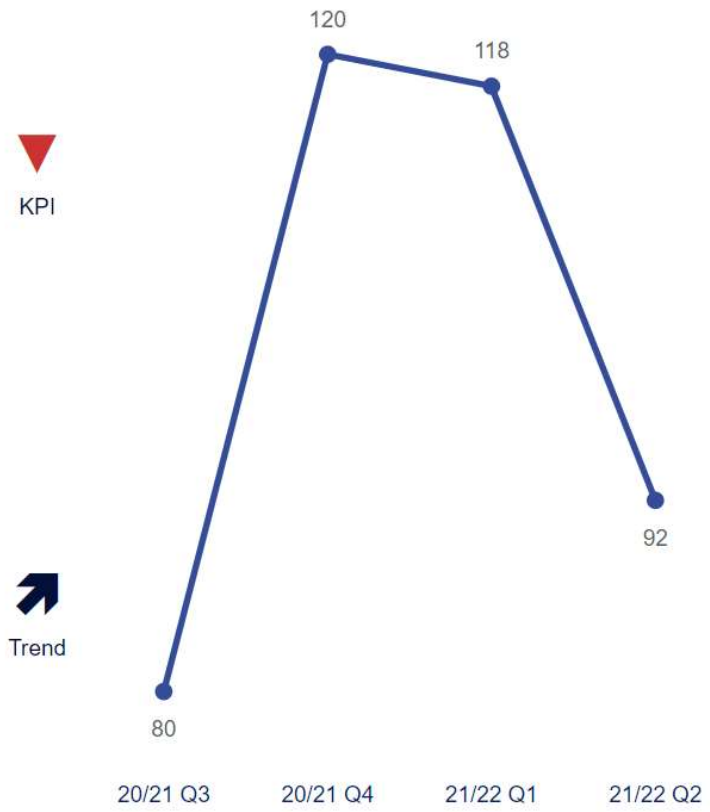
KPI Trend



Dynamic Organisation

Indexed Productivity

92
Target: 102



People Engagement Score

57.7%
Target: 66.0%

Key Project Milestones Average Days Slipped

36

Financial Sustainability

Available Cash Reserves

£51.34M
Budget: £51.34M

KPI

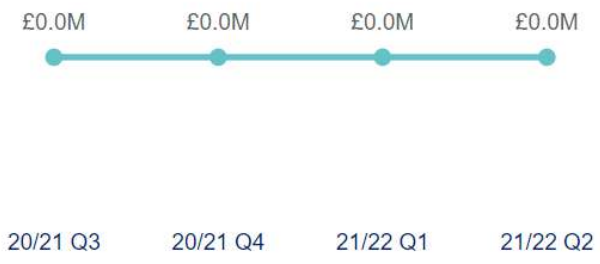
Trend

Non Pay Savings

£0.00M
Budget: £1.50M

KPI

Trend



Year To Date Operational Surplus/Deficit

£3.52M
Budget: -£2.40M

KPI

Trend

Financial Sustainability

Corporate Overhead %

31.3%
Budget: 31.7%

KPI

Trend

Maintenance Costs

1.2%
Budget: 3.8%

KPI

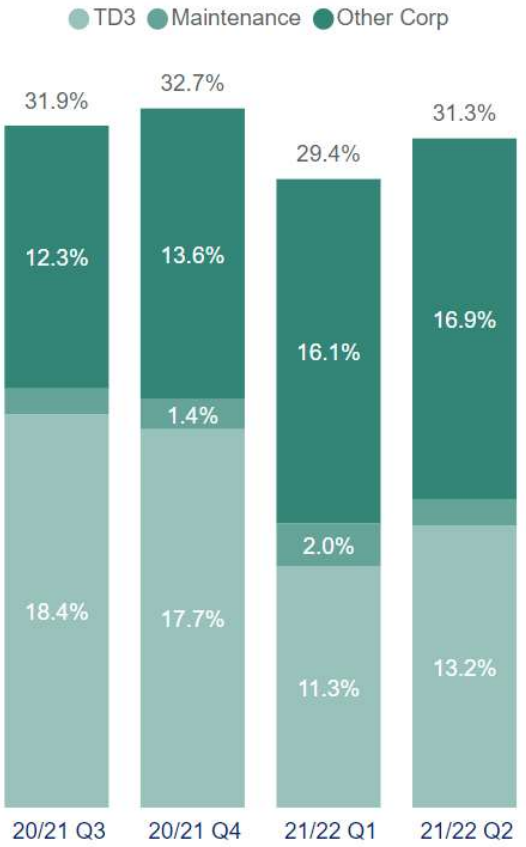
Trend

TD3

13.2%
Budget: 11.1%

KPI

Trend



Staff Costs

£22.80M
Budget: £24.75M

KPI

Trend

Cashable Benefits (12m Rolling) (SAMPLE DATA)

£0.60M

KPI

Trend

Medicines & Healthcare products Regulatory Agency

BOARD MEETING HELD IN PUBLIC

16 November 2021

Title	What has the MHRA achieved compared to each Quarter 2 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 Quarter 2 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 is the report on progress against the 2021–2023 Delivery Plan for the second quarter (Q2) of the reporting year. The Executive Committee (ExCo) has concluded that despite the challenges facing the Agency, good progress is being made. All but one of the nine items due this quarter were delivered on time. The Red-Amber-Green (RAG) ratings for Q2 have been reviewed and challenged, and there are 2 new Red, 2 new Amber / Red and 4 new Amber items this quarter. Remedial action for each of these has been agreed by the ExCo and will be monitored; details are provided below. The Amber items discussed by the ExCo and reviewed by the Board in Q1 are stable and showing some improvement. It will be important to maintain vigilance as we head into Q3 given wider pressures on the Agency and staff. The Board is asked to note this report and provide any comments they might have on the assurance given.

Introduction

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

3. At the end of the Q1 process everything was Green apart from 13 Amber and 4 Blue (completed) items; by the end of the Q2 process the following new ratings were added: 2 Red; 2 Amber/Red, 4 Amber (bringing the overall Amber total to 13, as some items have gone back to Green since Q1) and 8 Blue (bringing the overall Blue total to 16). Annex A shows each item in the Delivery Plan and their RAG status at the end of Q2.

Discussion

Performance against delivery of items due in Q2

4. Good progress has been made on delivery this quarter: 8 out of the 9 items due in Q2 were delivered on time and 1 slipped to next quarter ("*assessment of the linkages needed with the World Health Organisation (WHO)*" – see Amber items, this is now due for discussion at the ExCo in December). In addition, 3 items have been delivered early. See

the table below for a summary of the new completed items and ongoing reporting arrangements.

5. All of the items that were late in Q1 have now been delivered with one exception: the consultations enabling "new legislation to ensure safe access to innovative products". This was Amber in Q1 due to delays arising from resourcing pressures and a ministerial request for a rethink on the approach to clinical trials. Since then, good progress has been made: consultations for Point of Care manufacturing and the Early Access to Medicines Scheme were launched in September; the Sodium Valproate measures consultation was launched in November (following a delay in Government approval of the a launch date); and the Minister has agreed a new proposal for handling the clinical trials consultation with a revised delivery date of late November. The team propose this can go back to Green and aim to publish all consultation responses by end Q4, 2021/22.

6. When the Delivery Plan was published 23 deliverables were flagged as examples of work with particular patient interest, alongside the work on culture change. There has been an improvement in the status of these items since Q1. In Q1, 16 were Green and 7 were Amber, in Q2 4 are Blue, 14 are Green and 5 are Amber. These items are marked with an Asterix in Annex A and they continue to be monitored via the work associated with the Independent Medicines and Medical Devices Safety Review response.

Completed deliverable	Status, next steps and reporting
*7 By Q4, 2021/22 achieve **1 in every 4 UK GP practices signed-up to CPRD.*** (Janet Valentine)	Completed early. The Balanced Scorecard has a metric for population coverage and this will be tracked via that.
*15. Integrate with the Health Research Authority (HRA) and National Institute for Health Research Clinical Research Network (NIHR) to provide a **fast track approval for defined clinical trials** - criteria for approval agreed by end Q2, 2021/22.* (Martin O'Kane)	Fast track approval will be delivered via the MHRA / HRA Combined Review process for early phase cancer studies in England, Scotland, Wales. Next step is contacting potential sites to participate and a workshop ideally before end of 2021. We will update this item accordingly to allow reporting for Q3.
17. Support access to generics and biosimilars via more global harmonisation in approval standards; *seek **International Pharmaceutical Regulators Programme (IPRP) membership from** Q3, 2021/22* (LD – various) *[And]* *18. Take forward discussion of UK **Biosimilar guidance in the Access Consortium** from Q3, 2021/22*. (LD – various)	Both completed early. MHRA joined IPRP in June. We will participate in working groups and identify next actions. Companies are now able to apply for a new biosimilar access route. We published details of the new Biosimilar Work Sharing Initiative with links to the Expression of Interest form for the 5 regions.
*22. Publish public **consultation covering all key aspects of proposed new [medical devices] market access framework** by end Q2, 2021/22* [Blue] [*and] Publish a consultation response with finalised policy positions by end Q4, 2021/22.* [Green] (Camilla Fleetcroft)	This item was Amber in Q1 but has since been completed on time. Consultation was published on 16 September. Next step is publishing all consultation responses in Q4. We will now update this item accordingly to allow reporting for Q3.

26 Further action on valproate to drive compliance with the Pregnancy Prevention Programme (PPP). ***Enhance the valproate registry by extending the established England registry to include all antiepileptics*** *by end of Q2, 2021/22*. (Katherine Donegan)	Registry report due for publication on 30 September. Data will allow us to get a complete picture on the extent of prescribing of all antiepileptics in pregnancy. Reporting is happening via ongoing Independent Medicines and Medical Devices Safety Review response work.
35. Embed ***Delivery Plan in staff objectives*** *by Q1, 2021/22*; *[and]* ***monitor performance from Q2*** *with an updated reporting approach.* (Rachel Arrundale)	The Delivery Plan was shared in time for staff to update their objectives and we continue to improve the reporting process based on DPC / ExCo feedback.
38. Launch ***staff leadership action plan*** *by Q2, 2021/22.* (Vanessa Birchall-Scott)	Leadership paper and action plan was reviewed by the Board in September, work is underway and a further Board review is due in January.
40. Identify ***future workforce and talent needs*** *and deliver action to ensure we embed workforce planning by Q2, 2021/22.* (Vanessa Birchall-Scott)	Workforce planning is included in Transformation Programme (TP) design phase and consultation document organograms, capabilities and role descriptions including success criteria to provide current workforce plans. Delivery Plan requires an update in year 2 so reporting will continue.
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.* (Jack Turner)	The Medicinal Products Working Group has been set up, actions and internal monitoring will be confirmed by the Group and then we will update this item accordingly to allow reporting for Q3.
53 ***Publish our Public Engagement and Involvement Strategy****, which sets out how we can best include patients in our work by Q1, 2021/22.* (Rachel Bosworth)	Published online on 1 October and implementation of the actions within the strategy is being reported to the ExCo.

Agreed action plans for Amber deliverables

7. The Board reviewed the agreed action plans for Q1 Amber items in September. Resourcing was highlighted as a particular problem and 5 items have been granted approval for recruitment (following demonstration of a clear link to Delivery Plan priorities and a minimal risk of displacing staff). Now the Q1 Amber items are stable and showing some improvement: of the 13 items, 4 have gone back to Green following efforts by their teams and implementation of agreed mitigations; the remaining 9 have remedial action in train but pending at the time of writing. An update will be provided for all of these items in Q3 and several are on track to return to Green. This is summarised in Annex B.

8. There are now 2 new Red, 2 new Amber / Red and 4 new Amber items in Q2. Their agreed action plans are summarised in the table below. The Board previously challenged how confident the ExCo was in the accuracy of RAG ratings. For the Q2 process, the ExCo reviewed ratings with this in mind and have concluded that the ratings and the action plans looked suitable, but two items were elevated from Amber to Amber / Red ("use available cash reserves by the end of 21/22" and "upgrade our observational research infrastructure"

- this was to reflect the impact of unsuccessful delivery); and one item was moved from Green to Amber (work to "support staff during organisational restructuring" – this was due to the morale and capacity risks associated with staff exits). All three items with amended RAGs had their action plans updated accordingly.

9. At the time of writing, the outcome of the Agency Spending Review (SR) bid is unknown. It is a key dependency for several items in the Delivery Plan, for example the 2 new Red items and 2 Amber items ("upgrade our observational research infrastructure" and "deliver a new digital self-service platform") below have SR dependences. When the outcome of the Agency's bid is known, we will assess the impact on the Delivery Plan.

Deliverable	Issue and handling plan
RED – DELIVERY BY ORIGINAL DEADLINE NOT POSSIBLE	
*Finalise our **plan to overhaul costly legacy systems** by Q3, 2021/22 and start to **deliver improved service and savings** from Q4, 2021/22.* (TD[3])	**Issue:** We require a new supplier contract to be in place before we can work with that supplier to finalise technology plans and validate the systems delivery and technology savings plan. Additional scrutiny from HM Treasury on large procurements has contributed to a delay of up to 3 months. Delivering improved service and savings is dependent on the resolution of the issue above and the ability to undertake insourcing, which has been delayed due to recruitment freezes and the Transformation Programme (TP) consultation timetable. **Action plan:** This has been discussed at the ExCo and the Audit & Risk Assurance Committee. Given the delays we anticipate delivery of the plan to overhaul costly legacy systems by **Q1 2022/23**. With regards to delivering improved service and savings, we have completed our staff structure, validated the savings and are awaiting authorisation to recruit. The cost plan (ie SR or reserves) and savings schedule is being worked through with Finance and the TP. Given the delays, we anticipate savings will start from **Q1, 2022/23.**
*Have a **new Regulatory Management System (RMS)** in place by Q3, 2022/23*. (TD[3])	**Issue:** requirement for supplier contract to be in place as above. **Action plan:** engagement on system requirements has started in advance of a detailed Future Operating Model being delivered via the TP (which will clarify requirements but is a key dependency). We are information gathering through the Data Asset Review to identify which decisions on the minimum levels of data needed to safely regulate can be made before we can replace the RMS. This is also dependent on the new supplier contract. Given the delays however we anticipate delivery will be **Q4, 2022/23**.

AMBER / RED - DELIVERY AT RISK, HIGH IMPACT	
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.* (Finance)	**Issue:** utilisation of reserves is dependent on high-level of project activity in the second half of year. We are starting to see some slippage due to the combination of the unprecedented level of activity, coupled with organisational design implementation, which presents a risk and could lead to underutilisation of reserves. **Action plan:** the ExCo has agreed a plan to ensure optimal use of reserves and is closely tracking this. Resources Committee is approving and tracking all spend and is keeping ExCo informed.
Upgrade our observational research infrastructure *to enable timely and secure delivery of research data services: map out requirements by Q4, 21/22 and commence implementation of new systems by Q2, 22/23.* (CPRD)	**Issue:** work has started on observational research (OR) IT Business Case for migrating CPRD's IT infrastructure to the Cloud. Work is due to complete by end 2021/22. Scoping requirements for OR Trusted Research Environment on track but funding dependent on SR or retention of NIHR ring-fenced funds for IT development, which may be lost when the Agency loses its trading fund status. **Action plan:** funding has been requested in the SR bid. Negotiations with the Department are underway to retain CPRD ring-fenced NIHR funds at the end of 21/22, which would enable implementation to take place, subject to Strategic Change Committee approval.
AMBER - DELIVERY AT RISK	
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.* (TD[3])	**Issue:** delays to recruitment of web development team due to the need to align with the TP have resulted in start date for the project being delayed by 3 months, now due to start December 2021. Full planned completion of scope requires successful SR bid. **Action Plan:** 'pre-discovery' work is underway to minimise impact of the delay as well as agreement to use out-sourced resources where possible. Delivery on time is still possible with reduced scope focused on the standards sales website, but is at risk.
Map key partnerships for delivery *of our 21-23 objectives and refresh relationships with work programmes to maximise reach and impact from Q2 and in place by Q4, 2021/22.* (Policy)	**Issue:** work has had to be put on hold while resource is shifted to support the implementation of a new fees structure. Policy do not currently have the resource to deliver on both simultaneously. **Action plan:** this is captured in the new partnership portfolio structure and will be picked up again in due course. It is still possible that it might be brought back on track. We propose to mark it as Amber to flag the impact of the current pause.
Full assessment of the linkages needed with the WHO*, including in the context of our biological and control standards work by Q2, 2021/22.* (Policy)	**Issue:** we have prioritised efforts to making the Agency a WHO National Regulatory Authority (NRA) of record for COVID-19 vaccines, involving Ministerial clearance. This assessment has begun but has slipped as a result. The impact has been assessed as minor as its about strengthening an existing relationship and making the Agency an WHO NRA was a clear higher priority. **Action plan:** this is now due for discussion at ExCo in December.

Deliver HR support and guidance to staff during organisational restructuring **throughout Q1-Q4, 2021/22**. (HR)	**Issue:** restructuring understandably has an adverse effect on staff morale and exits carry risks to capability and loss of expertise. **Action plan**: mitigations are underway as part of the TP, for example via the staff communications strategy, regular 1:1s reflecting on career plans, the use of performance awards and the pivotal role allowance. This is also captured and monitored via the Corporate Risk Register and an indicator is being added to the Balanced Scorecard.

Recommendation

10. The ExCo has concluded that good progress has been made on the items due for delivery in Q2; the action plans for new Reds, Amber / Reds and Ambers are sufficient and now need careful monitoring; the Q1 Amber items are stable and, thanks to the action plans agreed during Q1 reporting process, showing some improvement. It will be important to maintain vigilance as we head into Q3 given wider pressures on the Agency and staff. Further work is planned for the third quarter when all of the new Chief Officers are in post on prioritising items in the Delivery Plan to help provide focus and tighter control where it matters. This will also include an assessment of the impact of the SR outcome on the Delivery Plan. The Board is asked to note this report and provide any comments they might have on the assurance given.

Jon Fundrey
3 November 2021

ANNEX A – OVERALL Q2 RAG SUMMARY

This table shows all items with a RAG status based on confidence in delivery. Items running late are indicated in the "Due date" column. Items that were flagged in the Delivery Plan as having particular patient benefit are asterisked in the number column.

#	Delivery Plan Deliverable	Due	Q1	Q2
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	G
2	Develop and publish our laboratory strategy and long-term plan, including a standards sub-strategy, by **Q4 2021/22**; and implemented from Q1 2022/23.	Q4, 2021/22	G	G
3	Upgrade our observational research infrastructure to enable timely and secure delivery of research data services: map out requirements by **Q4, 2021/22** and commence implementation of new systems by Q2, 2022/23.	Q4, 2021/22	G	A/R
4	Scale up two pilot primary care common data models to facilitate pharmacovigilance across different data sources: the Observational Medical Outcomes Partnership model by **Q1, 2022/23**; the 'Sentinel' model by **Q2, 2022/2023**.	Q1 / Q2, 2022/23	G	G
SCIENTIFIC INNOVATION; 3. Overhaul clinical trials system to support innovation and reduce time to approval				
5	Deliver two NIHR funded, real world pragmatic clinical trials through our innovative data-enabled clinical trials platform, with the first patients randomised in both trials by **Q3, 2021/2022**.	Q3, 2021/22	G	G
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	G
7	a. Launch a new service that assists in the rapid recruitment of patients into commercial clinical trials, with the first contract in place by **Q3, 2021/22** and offer this service to companies as standard by Q2, 2022/23	Q3, 2021/22	G	G
7	b. and by **Q4, 2021/22** achieve 1 in every 4 UK GP practices signed-up to our clinical practice research data service.	Q4, 2021/22	G	B
8	Consult on options for changing UK legislation to make conduct of trials generating real-world data easier by **Q4, 2021/22**.	Q4, 2021/22	G	G
9	Publish guidance on points to consider when using trial designs with a real-world data element to support a licence application by **Q4, 2021/22**.	Q4, 2021/22	G	G
10*	Develop use of Patient Reported Outcome Measures (PROM) via involvement in the "Setting International Standards in Analysing Patient-Reported Outcomes and Quality of Life Endpoints Data" international initiative from **Q1 to Q4, 2021/22**; and work up deliverables in 2022/23.	Q4, 2021/22	G	G
11	Deliver NHSX funded synthetic data research project by **Q4, 2021/22** and launch prototype synthetic data generation service by Q2, 2022/23	Q4, 2021/22	G	G
12	Finalise and promote the Innovative Licensing and Access Pathway (ILAP) Novel Trial Design Tool in partnership with the wider health ecosystem by **Q2, 2022/23**.	Q2, 2022/23	G	G

13	Deliver a set of work packages to ensure that AI as a medical device is underpinned by robust evidence to enable safer innovation by **Q4, 2022/23**.	Q4, 2022/23	A	A
HEALTHCARE ACCESS; 4. Develop and deliver future strategy and approach for access to medicines and devices				
14*	a. Put in place new legislation to ensure safe access to innovative products and to protect public health: timings agreed and public consultations begin from **Q1, 2021/22.** Next milestone: Launch all consultations – end Q3, 2021/22	Q1, 2021/22	A	G
14	b. consult on a national scheme to replace the FMD's safety features regulation by **Q4, 2021/22;**	Q4, 2021/22	G	G
14	c. formulation of final post-standstill policy during **2022**;	2022	G	G
14	d. resolution of any live regulatory issues following EU transition by **Q1, 2022/23**.	Q1, 2022/23	A	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	B
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	G
16	Reduce regulatory burden by working with stakeholders to identify which flexibilities introduced in response to COVID-19 are safe to embed by **Q3, 2021/22**.	Q3, 2021/22	G	G
17	a. Support access to generics and biosimilars via more global harmonisation in approval standards; seek membership of IPRP from **Q3, 2021/22**;	Q3, 2021/22	G	B
17	b. and take forward discussion of UK Biosimilar guidance in the Access Consortium from **Q3, 2021/22**.	Q3, 2021/22	G	B
18	Develop a mechanism to pilot joint clinical trial approval and clinical trial and licensing scientific and compliance advice via Access Consortium by **Q4, 2021/22**.	Q4, 2021/22	G	G
19*	Further develop the ILAP concepts and tools, in collaboration with the NICE and the Scottish Medicines Consortium (SMC) to create a world-class first port of call for medicines development and access by **Q3, 2021/22**.	Q3, 2021/22	G	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	G
21	Continued regulation of Northern Ireland, under the EU regulatory system, working closely with the Northern Ireland Exectuive to ensure continued access to life sciences products.	Ongoing	G	G
HEALTHCARE ACCESS; 5. Establish a new devices legislative framework to support safe innovation and ongoing access to products				
22*	Publish public consultation covering all key aspects of proposed new market access framework by end **Q2, 2021/22** [Blue] and Publish a consultation response with finalised policy positions by **end Q4, 2021/22.** [Green]	Q2, 2021/22	A	B
23*	Lay relevant SI by end **Q1, 2022/23**.	Q1, 2022/23	A	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	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.**	Q1, 2021/22	B	B
26*	a. Further action on valproate to drive compliance with the PPP. Enhance the valproate registry by extending the established England registry to include all antiepileptics by end of **Q2, 2021/22;**	Q2, 2021/22	G	B
26*	b. and make available a UK-wide digital annual risk acknowledgment form alongside defining the extension of the registry to the whole of the UK by end of **Q4, 2021/22.**	Q4, 2021/22	G	G
26*	Improve model of DEAC and its EAG by **Q3, 2021/22,** to ensure greater involvement of independent, scientific, technical, lay and clinical experts in regulatory decision making.	Q3, 2021/22	A	G
27	Deliver an options appraisal for our project to investigate the role of genetics in the development of adverse drug and vaccine reactions by **Q3, 2021/22**	Q3, 2021/22	G	G
28*	a. Review of teratogen use during pregnancy, and consideration of the strategies of other regulators by **Q3, 2021/22;**	Q3, 2021/22	G	G
28*	b. with independent patient and stakeholder input and expert advice by **Q4, 2021/22**;	Q4, 2021/22	G	G
28*	c. and, if required, updated action and guidance by **Q2, 2022/23.**	Q2, 2022/23	G	G
29*	a. Deliver enhanced signal detection process by **Q4, 2021/22**	Q4, 2021/22	G	G
29*	b. service enhancement and international opportunities to defined in **Q4, 2021/22**; c. and delivered in 2022/23.	Q4, 2021/22	G	G
30*	Agreed policy for a significantly enhanced transparency regime for medical device regulation by **Q4, 2021/22;** with key elements being delivered over 2022/23.	Q4, 2021/22	A	A
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	G
31	b. Roll out of automated inspection reports by **Q4, 2021/22**;	Q4, 2021/22	A	A
31	c. Identify new risk-proportionate approaches with our international partners by **Q4, 2021/22**;	Q4, 2021/22	G	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	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 – awaiting DHSC	G	G
33*	Deliver a world-leading approach to inspections with assurance that products are developed and manufactured to the highest standards **throughout 2021/22 and 2022/23.**	Ongoing	A	A

34*	Deliver a world-leading approach to enforcement with assurance that prompt action is taken to reduce criminal threats **throughout 2021/22 and 2022/23.**	Ongoing	G	G
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;**	Q1, 2021/22	B	B
35	b. monitor performance from **Q2, 2021/22** with an updated reporting approach;	Q2, 2021/22	G	B
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	G
36	Deliver accompanying TP and organisational redesign (staffing, governance, structures, processes) by **Q4, 2021/22** and post implementation support including benefits realisation from April 2022 onwards.	Q4, 2021/22	A	A
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;	Q1, 2021/22 **Slipped to July**	B	B
37	b. and deliver associated actions; refresh plan in **Q1, 2022/23.**	Q1, 2022/23	G	G
38	Launch staff leadership action plan by **Q2, 2021/22**.	Q2, 2021/22	G	B
39	Deliver HR support and guidance to staff during organisational restructuring **throughout Q1-Q4, 2021/22**.	Q1-4, 2021/22	G	A
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	B
40	b. and review workforce in **Q1, 2022/23** to identify follow up actions.	Q1, 2022/23	G	G
COLLABORATIVE PARTNERS; 10. Leverage international partnerships to drive better outcomes				
41	Development of an international strategy underpinning and aligned to the wider objectives in the Delivery Plan by **Q1, 2021/22.** *(The International Strategy was agreed by the Agency Board in July.)*	Q1, 2021/22 **Slipped to July**	B	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	B
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 **Slipped to Q3**	G	A
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	G

44	Establish greater international regulatory collaboration and alignment with the Access Consortium so patients benefit from timely access to high quality, safe and effective medicines from **Q3 2021/22.**	Q3 2021/22	G	G
45	Deliver a refreshed inspection network that adds strengths and international standing to the work of our inspectorate by **Q4, 2021/22.**	Q4, 2021/22	G	G
46	Collaborating with other country regulators to provide quicker access to the next generation of cutting-edge treatments, while maintaining the highest safety standards by **Q4, 2022/23.**	Q4, 2022/23	G	G
47	Actively engage in ongoing trade negotiations (with the USA, Australia, New Zealand and others), putting forward a positive regulatory agenda and enhancing areas of regulatory cooperation **throughout 2021-23** as per the DIT timescales	Ongoing	G	G
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.**	Q1, 2021/22	B	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	G
50	Map and identify the most important partnerships for delivery of our 2021-23 objectives and refresh strategic relationships with detailed work programmes developed to maximise reach and impact across the system from Q2 and in place by **Q4, 2021/22.**	Q4, 2021/22	G	A
51	Continue delivery of our commitments to the DHSC and ministers **throughout 21-23.**	Ongoing	G	G
52	Run partnerships meetings with the DAs and wider stakeholder groups to inform and involve them about the delivery of their priorities, quarterly **throughout 21-23.**	Ongoing	G	G
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.**	Q1, 2021/22 **Slipped to 1 October**	G	B
54	Develop and deliver further communications to support the evolution of our COVID-19 vaccines strategy from **Q2, 2021/22.**	Q2, 2021/22	G	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	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	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	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~~1~~2/22~~3~~** [nb typo with date – impossible to balance costs in 2021/22, this deadline must have been for *creating the leaner structure* rather than *balancing costs*]	Q3, 2022/23	A	A
59	Use available cash reserves to fund necessary systems investments, operational deficits and restructuring costs until the end of our Trading Fund status at the end of **2021/22.**	End 2021/22	G	A/R
60	Develop, consult on (Q3, 2021/22) and implement a new fee structure by **Q2, 2022/23.**	Q2, 2022/23	A	G
61	Reduce corporate costs by 15% by the end of **2022/23.**	End 2022/23	G	G
62	Reduce non-pay costs of £60m by £6m per year through contract renegotiation and contract management by the end of **2022/23.**	End 2022/23	G	G
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	R
63	b. and to have a new regulatory management core system in place by **Q3, 2022/23**.	Q3, 2022/23	G	R
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	A
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	G
66	Work with the HRA to deliver an enhanced clinical trials service by **Q4, 2022/23.**	Q4, 2022/23	G	G

ANNEX B – UPDATE ON Q1 AMBERS

This table summarises the status of the Q1 Amber items: 4 been brought back to Green and 9 remain Amber as remedial action is in hand but pending. RAG will be reassessed in Q3.

Deliverables that were Amber in Q1	Status
Brought back to Green in Q2	
Put in place new legislation *to ensure safe access to innovative products and to protect public health: timings agreed and public consultations begin from Q1, 2021/22*.	New proposal accepted by minister, good recent progress.
Publish public ***consultation covering all key aspects of proposed new market access framework*** *by end Q2, 2021/22 and publish a consultation response with final policy positions by end Q4, 2021/22.*	First half is Blue as the consultation was published on 16 September. the second half is Green given economist resource has now been secured.
Improve model of **Devices Expert Advisory Committee (*DEAC)*** *and its Expert Advisory Groups by Q3, 2021/22, to ensure greater involvement of independent, scientific, technical, lay and clinical experts in regulatory decision making.*	Following a positive reception of the proposal at DEAC on 16 September this has gone Green.
Develop, consult on (Q3, 2021/22) and implement a ***new fee structure*** *by Q2, 2022/23.*	Policy have moved resource to prioritise this work; note impact on Amber partnership mapping work.
Amber as agreed mitigation in hand but pending	
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.*	New resource stalled until job matching during transformation process. Soonest we'll be able to advertise is November. Reassess RAG after.
Lay relevant Statutory Instrument (SI) *by end Q1, 22/23*; and *publish key guidance documents by end Q3, 22/23 with ongoing stakeholder engagement over 22/23 to prepare them for the* ***new framework****.*	Remedial action identified at ExCo and new analyst starts on 15 October – then need to catch up on delay. Reassess RAG in Q3.
Resolution of any live **regulatory *issues following EU transition*** *by Q1, 2022/23.*	Amber given level of challenge. Reassess RAG after we have progressed via transformation.
Agreed policy for a significantly ***enhanced transparency regime for device regulation*** *by Q4, 2021/22; with key elements being delivered over 2022/23.*	Progress has been made but delivery is dependent on SI and whether our current IT systems can be improved in order to reliably process and prepare the data for publication; reassess RAG in Q3.
Deliver ***world-leading approach to inspections*** *with assurance that products are developed and manufactured to the highest standards throughout 2021/22 and 2022/23.*	Amber given level of challenge. Reassess RAG after we have progressed via transformation.
Roll out of **automated inspection reports** by Q4, 2021/22.	Amber given level of challenge. Reassess RAG after we have progressed via transformation.
Deliver **accompanying TP** and org redesign by Q4, 2021/22 and post implementation support including benefits realisation from April 2022 onwards. [a*nd]* **Implement org design**, creating a new, leaner structure for the organisation and balancing our costs by **Q3, ~~2021/22~~ 2022/23**	Good progress being made but ExCo decided to leave as Amber given level of challenge. [nb correction on date – not possible to balance costs in 2021/22, this deadline must have been for *creating the leaner structure* rather than *balancing costs*]

Medicines & Healthcare products Regulatory Agency

BOARD MEETING HELD IN PUBLIC

16 November 2021

Title	What has the Innovative Licencing and Access Pathway delivered and how will it be developed?
Board Sponsor	Marc Bailey
Purpose of Paper	Strategic Direction

What has the Innovative Licencing and Access Pathway delivered and how will it be developed?

1. Executive Summary

1.1 Following the UK leaving the European Union, the Medicines and Healthcare products Regulatory Agency (MHRA) became a sovereign regulator, a change that has opened up significant opportunities. These opportunities have been capitalised on through the creation of a new ambitious expedited route to market for medicines, the Innovative Licensing and Access Pathway (ILAP).

1.2 The Board is asked to consider the ILAP activity to date, the proposed direction of travel and recommend any other areas for development.

2. Introduction

2.1 The Innovative Licensing and Access Pathway (ILAP) has been operational since the 1st of January 2021. ILAP offers a flagship Agency service, providing a platform for accelerating the time to market for innovative medicines. A key aspect is how the ILAP platform supports a novel framework for closer collaboration with ILAP permanent partners, the National Institute for Health and Care Excellence (NICE), the Scottish Medicines Consortium (SMC) and more recently the All Wales Therapeutic & Toxicology Centre (AWTTC). The main components of the pathway are the Innovation Passport designation (IP), the Target Development Profile roadmap (TDP) and the tools of the TDP toolkit. ILAP covers the entire development programme from before First in Human Studies through to supporting a life cycle approach to approved medicines (real world data collection and new indications).

2.2 This paper provides an update on what the ILAP has delivered so far and the future operational and strategic aspects of the pathway. This includes a summary of the metrics of activity, the joining of a new partner (AWTTC), the integration of the patient voice and the future plans to continue to evolve the ILAP based on experience and alignment with policy documents such as the Life Sciences Vision. The paper asks the Board to note the progress so far and requests input on what additional features should be built into ILAP, where further efficiencies might be found and the future direction for development.

3. What has the Innovative Licencing and Access Pathway delivered?

Launch of a new visible pathway to access for medicines

3.1 The principles of ILAP were formed through strategic working groups as part of the preparations for leaving the EU regulatory framework and building on successful relationships and interactions in the wider healthcare ecosystem. The aim of the ILAP is to deliver safe and early patient access to innovative medicines, ensuring through the unique partnership working between MHRA and HTA bodies that products that are developed through ILAP are both regulatory and access ready.

3.2 The launch of the ILAP created a new visible and ambitious pathway to patient access for the UK following exit from the EU. The pathway helps ensure that the UK remains relevant and attractive to innovators developing medicines as a first and early launch market. Feedback has suggested that companies who may have not wished to engage early in the UK are now taking a 'second look' based on the ILAP offer – an example from an email quote from a law firm who advise industry:

'Generally speaking, ILAP is attracting a lot of interest. Companies which were not interested in entering the UK market in the first tranche are reconsidering their position. The fact of having access in a coordinated manner to all relevant stakeholders is a PLUS.

3.3 In addition, ILAP offers a visible national (and international) signal of a company's intent to develop medicines in a completely unique way. This is referenced for example in the UK Life Sciences Vision published in July 2021:

'*For medicines, the MHRA will work with NHS partners and international regulators to deliver the fastest regulatory assessments and decisions. This will involve innovative regulatory models, building on the approaches developed for the Early Access to Medicines Scheme (EAMS) and the Innovative Licensing and Access Pathway (ILAP)*'.

A new medicine designation, the Innovation Passport (IP) Designation:

3.4 The first step in the ILAP is the Innovation Passport designation application, a mandated entry point. The first Innovation Passport approval was approved in February 2021 for Belzutifan (a treatment developed for adults with von Hippel Lindau disease). The IP decision is made at the ILAP cross partner Steering Group, with all 4 ILAP partners (MHRA, NICE, SMC & AWTTC). Importantly and in keeping with the goal to embed the patient voice in the ILAP right from the start, patient representatives contribute to the decision making at the ILAP Steering Group through their attendance and discussions. Patients have provided feedback on the need to be pragmatic in the approach for rare diseases and highlighted the importance of patient reported outcome measures.

3.5 The IP is open to developers at the pre-clinical trial stage and the entrance criteria for ILAP are broad and inclusive. At the time of writing this paper there have been:

- 65 applications for the IP designation
- 36 approved
- 7 refused
- the remaining 22 applications are pending assessment and decision

3.6 This level of interest far exceeds the predicted activity based on regulatory intelligence at the end of the transition period (30-40 applications predicted in the first year based on discussions with industry). Applications for the IP have been on average 5-6 per month with a peak of 10 applications in one month in the summer. The highest proportion of applications has been seen in the oncology area, but there are also designations across other therapeutic areas. About a quarter of applications are at the early stage (First in human study not yet initiated) with half at the mid stage (pre-phase 3 not recruiting).

Therefore, we can conclude that ILAP has been broadly welcomed by the pharmaceutical industry and that there have been a significant number of early adopter companies. It is expected as evidence accumulates of the benefits of the ILAP approach that more companies and sponsors will engage (including not-for-profit groups with repurposed medicines).

3.7 The agency doesn't currently publish information on IP that are approved or refused. However, companies that have received IP have had press releases, indicating the importance of the designation step to their development programmes. As an example, from an article published in the Financial Times (19/10/2021):

US biotech signs deal with NHS to deliver cheaper cancer drugs

'*These two treatments have been granted Innovation Passport designations through the UK's Innovative Licensing and Access Pathway (ILAP), a new programme to accelerate regulatory approvals. Boris Johnson's government hopes faster approvals will attract companies to develop and license their medicines in the UK, despite the country's small percentage of the overall global drugs market. Nallicheri described the "incredibly innovative" ILAP process as "the cherry on the cake" in striking the deal with the NHS'*.

3.8 This quote demonstrates the clear importance of the 'system' working together through ILAP partners to deliver important medicines to patients.

A roadmap of activity, the Target Development Profile (TDP)

3.9 A cross partnership team of experts will help define the TDP activities based on a product's characteristics. The TDP will define key regulatory and development features, identify potential pitfalls and create a road map for delivering early patient access. Sections of the TDP are:

i. Kick-off meeting and stakeholders
ii. About the product development
iii. Future development and evidence generation (including if the developer is intending to conduct clinical trials in the UK)
iv. Scientific advice
v. Patient engagement including the use of Patient Reported Outcome (PRO) measures
vi. Special populations
vii. Product life cycle
viii. Issues to be discussed at the kick-of meeting

IP to TDP process

3.10 An important step in the ILAP is supporting the IP holders to gain TDP, which is the process by which innovators will be able to develop products that are regulatory and access ready. To date we have received 9 TDP requests. These requests are progressing through to meetings and delivery of the TDP roadmaps.

As part of the strategy to convert IP to TDP we have written to all IP holders who have late stage products to understand their intentions regarding engaging with the TDP process and will replicate for the earlier stage products in due course. It is proposed in the future (as resources allow), that a positive IP letter will be issued with specific dates for the TDP meeting. To note, some early applications were for Project Orbis submissions (a programme coordinated by the US Food and Drug Administration (FDA) to review and approve promising cancer treatments) and therefore not all late stage IP holders will require an immediate TDP for their lead indication. However, as per the lifecycle approach to the TDP it is expected that over time the TDP will be sought for follow on new indications.

TDP tools of the Toolkit

3.11 The ILAP toolkit includes innovative and flexible activities designed to help bring clinically important and promising medicines to patients faster and more efficiently. It reflects a lifecycle approach to evidence generation, alongside some mandatory aspects to ensure regulatory compliance. The current tools of the toolkit are:

i. Adaptive Inspections is designed to support the over-arching ILAP and enable transformed regulation. It will support the non-clinical, clinical and manufacturing design and development pathway to ensure protection of patients and reliability of results.
ii. Certifications provide developers with an enhanced official regulatory review of packages of Common Technical Document (CTD) data. The process will provide applicants with specific and actionable feedback on the expectations for marketing authorisation and the regulatory requirements
iii. Continuous Benefit Risk Assessment integrating Real World Evidence is a proactive approach to data collection and post authorisation vigilance is key in supporting approval of innovative medicines. This tool helps ensures that the agreed approach delivers the right data, filling potential gaps in evidence within the right timeframe.
iv. Clinical Practice Research Datalink (CPRD) Assisted Patient Recruitment can help to efficiently locate patients across the UK who are potentially eligible for a clinical trial via a centralised search of the CPRD electronic health records (EHR) database, followed by GP clinical review
v. Enhanced patient engagement is a key component of MHRA's broader commitment to be a patient and public-focused regulator – putting patients and the public at the centre of our regulatory decision-making, providing opportunities throughout the ILAP for companies to consider the patient's experience and voice in a meaningful way in how they develop their innovative products
vi. Innovative and Flexible Licensing Routes is intended to provide support and guidance in the choice of routes for products in the ILAP, providing expedited timelines for review, pragmatic approaches to evidence requirements and international options where appropriate and available
vii. The novel methodology and innovative clinical trial design tool is designed to establish a system and culture that is receptive and supportive of novel methodologies in both the clinical and pre-clinical space to develop new medicines or new indications
viii. Rapid Clinical Trial Dossier Pre-Assessment provides sponsors of clinical trials with expert feedback from MHRA clinical trial unit assessors on their clinical trial

authorisation (CTA) application dossier before it is formally submitted, reducing the chance of a 'Grounds for Non-acceptance'

3.12 There is ongoing work through the project team to consider the fees for the different tools of the toolkit and overall resourcing and fee structure of delivering the TDP. Based on the very strong demand to date, the Agency is looking for ways to make the ILAP more efficient as the number of applications increases. Implementation of the TDP roadmaps and tools is an important step to support the ambition of a faster time to market, and a product project managagement approach is under active discussion.

Enhanced Patient Engagement, the ILAP patient and public reference group

3.13 ILAP offers a unique opportunity to embed the patient voice right from the beginning of the drug development process through to regulatory decision making and beyond. An ILAP Patient and Public Reference Group has been set up as an initial six months pilot (activity expected to continue and grow). The pilot will report early next year with recommendations based on experience to date. 16 patient and public members have been appointed by the MHRA, NICE and SMC. Since August, members from the group have rotated onto the ILAP steering group in threes to contribute to the discussions on the approval or not of the IP designation. Patients have provided valuable contributions to the discussions on the award of the Innovation Passports, for example around the challenges of being a rare disease patient. These interactions allow patients to voice their views right from the start of the ILAP, ensuring that the IP designation reflects cross stakeholder opinion. The group is also supporting the development of the ILAP Patient Engagement Tool and best practice guidance.

Comparison to other regulatory international offers, PRIME and Breakthrough designation

3.14 ILAP builds on the success of other regulatory offers but has a number of globally unique aspects when compared to other medicine designations / expedited programmes, such as the European Medicines Agency's PRIME and the US Food and Drug Administration (FDA) Breakthrough designation:

- ILAP involves patients in the Innovation Passport designation decision
- ILAP covers the whole life cycle of a medicinal product including supporting the development of multiple indications in a lifecycle approach versus single indication, with a specific focus on real world data collection and continuous benefit risk assessment
- ILAP Innovation Passport is open to submissions from non-clinical data versus requirements for clinical data
- ILAP includes a partnership between the medicines regulator and HTA bodies, including co-decision making at for example the Innovation Passport designation decision
- ILAP IP designation is linked to a portfolio of activities around the creation of the TDP and the ILAP toolkit offers diverse and unique tools to support innovative and efficient approaches to drug development

4. How will ILAP be developed?

Deliver better patient and public involvement for medicines

4.1 Patient and public involvement will become more prominent in the ILAP as the pilot on engagement and involvement concludes and the enhanced patient engagement tool matures. Patients will become systematically embedded in the partnership decision making point of the IP designation, demonstrating visible and meaningful involvement of patients right from the start. This engagement helps fulfil part of the agency's patient strategy and address some of the recommendations from the 'First Do No Harm' report. Benefits of the engagement include the agency and partners better understanding patient needs, companies developing medicines that have meaningfully considered the patient voice and for patients to have the opportunity and recognition in engaging with the ILAP partners.

Main route to licensing innovative medicines

4.2 The ILAP entry criteria are broad and inclusive. The creation of the TDP and toolkit are attractive offers to industry with partnership working and the potential for faster approvals and access. Based on strong early interest and as the ILAP develops (tools and competencies), the ILAP could become the main route for medicine licensing and access.

Expansion of ILAP activities to include other organisations

4.3 Following discussions with Welsh colleagues around the role of the ILAP and agreement by Welsh Ministers, the AWTTC joined partners in the ILAP activities in October 2021. This included considering if a product meets the criteria for an Innovation Passport. AWTTC involvement is seen as important step in ensuring that there is awareness of the innovation pipeline across the health ecosystem. There is also interest in the ILAP from other organisations such as the National Institute for Health Research (NIHR) and Health Research Authority (HRA). The MHRA has been working with the Accelerated Access Collaborative (AAC) and the ILAP processes have supported some of the early stage product workstreams for advanced therapy medicinal products (ATMP) and histology independent indications.

More information in the public domain

4.4 The ILAP steering group will consider ways to provide more information in the public domain around the activity of the ILAP, including publishing summary statistics. This information will also be shared with the Department of Health & Social Care (DHSC) and the Office of Life Sciences who have responsibility for the delivery of the Life Sciences Vision of which ILAP forms part.

Update to the guidance and support for applicants

4.5 Based on experience and questions and feedback from external stakeholders we will update our webpage towards the end of the year to provide more guidance on the application process. We will also develop some case studies demonstrating the benefits of engagement with the ILAP and bringing the guidance to life.

ILAP Summit

4.6 In order to strategically advance the ILAP concept, an ILAP Summit is proposed for January 2021. This summit will have a closed session for partners to discuss progress to date, challenges and future opportunities. This will be followed by an open session with external partners (eg industry, academics, patients and other organisations in the health system) to gather feedback and present a summary on the 1-year activity of ILAP. Further information will be made available in due course.

Enhanced digital offer

4.7 An enhanced digital offer for applicants applying for an IP and TDP is being developed by the MHRA and will launch in January 2022. This system will also provide an opportunity for more automated communications within the partnership and an enhanced operational front door to applicants.

New tools to be added to the toolkit

4.8 HTA bodies in the ILAP will launch a new access tool to support the cost effectiveness aspects of product development. Other additional tools of the toolkit are also actively being considered.

Leading the way on precision medicines

4.9 Supporting the ambition of the Life Sciences Sector Deal 2, the ILAP provides a clear UK regulatory pathway for genomic medicines and genomic tests, helping to accelerate developments in precision medicine by building a roadmap (TDP) to help developers understand the regulatory and access requirements. In order to ensure the visibility of ILAP for these types of development programmes, the web page will be amended with specific information to signpost the benefits of ILAP engagement.

Developing innovative access for devices

4.10 There is considerable interest from industry and patients in creating an innovative pathway for access to medical devices. Building on the successes of the ILAP principles, but in a different regulatory framework, exploratory work is underway in partnership with NICE, Health Technology Wales and the Scottish Health Technologies Group. The aim is to offer a pathway for innovative devices that provides key support in their development plan, with the additional option for providing exceptional use authorisations where there is a clear unmet clinical need that the device can solve.

4.11 The pilot for the devices pathway will look to support the goals of the Life Sciences Vision by focusing initially on the areas of mental, health, cancer diagnostic and supporting the NHS COVID-19 recovery.

5. Recommendation

5.1 The Board is asked to consider the ILAP activity to date, the proposed direction of travel and recommend any other areas for development

Marc Bailey
November 2021

Medicines & Healthcare products Regulatory Agency

BOARD MEETING HELD IN PUBLIC

16 November 2021

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

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

1. Introduction

The Organisation Development and Remuneration Committee (ODRC) met on 1st November 2021. We were pleased to welcome Junaid Bajwa to his first meeting as a member of the Committee. Due to connection problems the meeting was not quorate for all the agenda items. It was agreed that actions would be signed off formally at the December Meeting.

The agenda for the meeting covered:

- ODRC Role and Terms of Reference
- A review of the Services that will be provided by the Agency in the future and how they will be implemented as part of the Transformation Programme
- A review of the HR Deliverables within the Transformation Programme
- Review of HR Balanced Scorecard Metrics

2. Executive Summary

2.1. **Role of ODRC** – The Board had requested that the ODRC take a step back to concentrate on its strategic role to advise the Agency and provide assurance to the Board that the Agency has an effective organisation, processes and culture in place to manage and develop the workforce to deliver the Agency's strategy and services. The Terms of Reference will be updated accordingly and finalised at the December Meeting.

2.2. **Agency Transformation**

2.2.1. Work has started to define what services the Agency will be able to deliver within the available budget and financial constraints. The committee emphasised that any framework for services developed must be sustainable and be able to operate sustainably within the financial resources available to the Agency.

2.2.2. Recognising the inherent challenges, it was suggested that scenarios be developed to guide the prioritisation. Members of the Executive Committee (ExCo) will then work together to make a final recommendation on the services that will deliver most value to patients and public health within the available budget and within the size and shape parameters that have been shared with staff during the consultation process.

2.3. **HR Deliverables within the Transformation Programme**

2.3.1. The Board can be assured that due process is being followed for the voluntary exit (VE) process and that where necessary Cabinet Office approval is being sought to finalise arrangements for a small number of cases.

2.3.2. There is an extensive programme of work planned which is on track to map roles and populate the new organisation at the levels below the Chief Officers who have now all been appointed.

2.3.3. The full extent of the change will not be available until after the mapping process has been completed at the end of November.

2.3.4. The committee requested that data be made available to ensure that there was alignment of the organisational change with the budget and the services that the Agency was required to deliver.

2.3.5. The committee would continue to review the progress of the organisational change including feedback on morale and motivation.

2.4. **Balanced Scorecard**

The committee supported the inclusion of additional metrics on the balanced scorecard to measure performance on diversity and inclusion, engagement including feedback from staff surveys, as well as metrics on numbers and staff retention/turnover.

3. Progress of the Agency Transformation

Assurance can be given to the Board that there has been substantial progress to determine the scope of the services that the Transformed Agency will be deliver. The work is not yet complete but there are plans in place to complete the work with the new Chief Officers and their management teams. This will deliver outcomes with clarity on who is responsible for delivery and within what timescale. Progress will be reviewed in December.

It was agreed that the work on services needs to be linked with the work on fees so that the organisation is of a size that is financially sustainable through delivery of the services with a workforce that is highly motivated and has the appropriate skills and capabilities.

Given the pressure on budgets and the need to achieve efficiencies, it was recommended that a scenario should be developed that supported a reduction in cost base to understand what this would mean for the future. This would help to prioritise services and a more sustainable model could then be developed as more information on fees, financing and demand from customers became available.

ExCo will evaluate the outcomes bringing together what services can be delivered with the level of budget that is available and the greatest impact on public health before proposing what activities should be stopped.

4. HR Deliverables within the Transformation Programme

The progress of the voluntary exit (VE) programme was reviewed. The board can be assured that due process is being followed and that where necessary Cabinet Office approval is being sought to finalise arrangements for a small number of cases.

The current staff within the Agency are employed on a variety of different types of contract including permanent, fixed term and temporary contracts. Reductions in staff on all contract types will be required to achieve the proposed size and shape.

A key next step will be completion of the mapping exercise which will incorporate feedback from the consultation process and will be completed by the end of November. This will identify where there are gaps in skills and capability, as well as where people can be slotted into new roles within the future organisation. This is a critical next step to understand the scope and scale of change for individuals at a personal level and the number of redundancies that will be required.

The committee stressed the importance of making appointments as quickly as possible to minimise uncertainty for individuals and to enable new appointments to be made as quickly as possible.

It was stressed that the quality of conversations with staff at this time was critical to retain key skills and capabilities so that morale and motivation are maintained for the majority of staff who will remain in the new organisation.

The committee asked for additional information on the scope and scale of the number of people who will be made compulsorily redundant and how many will be slotted into the new structure. They also sought assurance on how moral and motivation of staff would be maintained and improved.

The committee emphasised the importance of close alignment to the transformation work on the scale and scope of the new services and the costs of delivering these with the size and shape of the organisation. It was emphasised that this would need to be an iterative process involving close collaboration between HR, Transformation and Chief Officers and their teams.

5. ODRC Terms of Reference

It was agreed that the ODRC will take a more strategic role operating at a similar level to the Audit & Risk Assurance Committee (ARAC) and the Patient Safety & Engagement Committee (PSEC). The primary objective of the committee is to give assurance to the Board that the Agency has the appropriate culture, capabilities and procedures in place to lead, manage and develop members of the workforce to enable and motivate them to deliver the Agency's strategy and objectives.

A future agenda plan will be developed for agreement at the December meeting.

Opportunities to work jointly with other assurance committees will be evaluated. A request will be made to ARAC to ensure that Internal Audits pertinent to people matters are shared with ODRC.

Amanda Calvert
Chair
ODRC
November 2021

Medicines & Healthcare products Regulatory Agency

BOARD MEETING HELD IN PUBLIC

16 November 2021

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

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

1. Executive Summary

1.1 The Audit Risk and Assurance Committee (ARAC) met on 2 November. We were very pleased to welcome Paul Goldsmith, Non-Executive Director to his first meeting as a member of the Committee. The Board assigned three actions to ARAC, all of which have been completed.

2. Action: Financial sustainability ARAC to Review the Agency's financial performance in the first six months of 2021/22 together with the cost-effective utilisation of the Agency's reserves.

2.1 ARAC based its assurance on the mid-year financial report and the Agency's "most likely outcome model" which provides the current estimate of the MHRA's financial position in 2022/23 and 2023/24. ARAC was assured that the Agency has sufficiently comprehensive information to monitor and manage its finances. Expenditure for the first half of the year was around 10 percent less than budgeted (largely explained by lower change costs). Financial forecasts up to the year end (31 March 2022) indicate that change costs should increase resulting in the annual financial deficit being close to that planned.

2.2 We reviewed the assumptions underpinning the financial forecasts including an adjustment for optimism bias and were assured that these were robust. Utilisation of financial reserves in the first half of the year has been slower than planned and expenditure on digital projects in 2021/22 is now likely to be less than budgeted. The Agency's most recent forecasts indicate an acceleration in expenditure on digital projects over the remaining six months. We took some assurance from the application of more rigorous criteria for prioritising digital projects to refocus resources better (see discussion of digital risk below) and that a number of projects are well advanced so should help secure this. Digital spend does however remain a risk requiring ongoing management. The Agency has also identified a number of other business critical projects which could be quickly initiated.

2.3 We discussed the risks inherent in the "most likely outcome model" particularly as any critical spend deferred to 2022/23 would need alternative funding as the change in trading fund status will mean that the Agency's financial reserves will no longer be available. At present the outcome model is tentative until the final design of the Agency's new operating model and its underlying cost base are agreed (before Christmas) and the outcome of the Agency's current funding bid as part of the recent Spending Review is known. ARAC will review the financial model again at its next meeting in January and report to the Board in February once these remaining uncertainties have been resolved. We are pleased that as part of contingency planning Finance are modelling a number of different options that might be activated in different financial scenarios.

2.4 We also discussed two other aspects of the Agency's financial management. Firstly, making a clear distinction between corporate overheads which should be allocated to all of the MHRA and those that can be more directly associated with a specific business activity, for example making transparent the cost of a digital system on which a specific regulatory or other function depends to incentivise ownership of the investment and how it is managed. Secondly as the Agency has to generate more revenue, being confident that business planning is sufficiently sophisticated, integrated and consistently applied.

3. Action: Review and consider higher risk ratings on the implementation of the new Device Regulations and the implementation of the Future Operating Model so that an updated Corporate Risk Register can be submitted to ARAC for further scrutiny.

3.1 This was covered as part of the corporate risk register review in paragraphs 5.5 and 5.6.

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

4.1 This was also covered as part of the corporate risk register review in paragraphs 5.7-5.9.

5. Other issues covered by the Committee

Preparation for change in Trading Fund status

5.1 Following the change in the Office of National Statistics' classification of the MHRA, the Agency will cease to be a Trading Fund from 1 April 2022 and will become closely aligned to the Department of Health and Social Care's financial control regime. This is a major change which needs to be managed as a formal project.

5.2 The Agency has produced a detailed plan as to how the change will be implemented. The plan draws on the experience of the Driver and Vehicle Licensing Agency which has undergone the same transition. We were assured that the plan is comprehensive and reflects good engagement with the Department. We discussed how a number of key risks will be managed including: the culture change that needs to be secured so that the enhanced financial reporting required is embedded across the Agency; and managing end of year financial balances and provisions.

5.3 Internal Audit are now reviewing how the plan will be implemented over the next four months together with early progress and will report to the Committee at its next meeting at the end of January

Risk Management

5.4 We reviewed the corporate risk register and were assured that this was well focused and addressed the key risks which the Agency faces. To enhance the Committee's assurance we focused on three risks in more detail: future operating model; implementation of the new medical devices regulations; and digital implementation.

Future Operating Model

5.5 The risks associated with the successful implementation of the new operating model are identified with mitigating actions. We were assured that good progress has now been made in agreeing the new structure of the Agency and the supporting systems although there is more to do on the latter .The important consultation with MHRA staff is almost complete and it is now time-critical that the new operating model is formally agreed. We observed that something of an impasse had developed in that there has been a reluctance to begin the design of new digital solutions until there was certainty over the new business systems and processes and that this has contributed to the digital underspend. The recent prioritisation of digital projects should help resolve this.

New medical devices regulations

5.6 We were assured over how risks were being managed. An important milestone is the public consultation now underway. Safety Connect will be an important component of the delivery of the new medical devices regulatory framework. This is currently subject to an Internal Audit review which will report to ARAC in January. The Patient Engagement and Safety Committee and ARAC will also hold a joint meeting in February to review progress with Safety Connect.

Digital implementation

5.7 The key risks to the successful implementation of the Agency's digital programme are documented but the Committee sought additional assurance as to how these are being managed particularly as progress with implementation is slower than planned. We received an update on progress with the Agency's Digital Roadmap and noted that requirements for new or enhanced systems have increased which is not sustainable. We sought assurance that the Agency has sufficient internal capacity to support the delivery of the Roadmap and understand that the balance between bought in and internal capacity and skills is being realigned.

5.8 We were assured by and support the Executive's decision to designate five key strategic areas, particularly the Regulatory Management System, which the Agency will prioritise. We also support the introduction of more rigorous criteria to determine the priority which will be given to other projects. Success will depend, however, on the criteria being understood, complied with and appropriately scrutinised before projects are initiated.

5.9 The Agency is currently tendering for a new digital supplier and the contract is likely to be awarded over the next couple of months. This contract is strategically important to the MHRA and the Committee has asked to be updated on progress at its next meeting when the Agency's new Chief Technology Officer is in place. We will seek assurance on the framework which the Agency puts in place to manage and monitor the contract.

External Audit

5.10 The National Audit Office (NAO) supported by KPMG presented a helpful briefing on some of the accounting issues which the Agency will need to address in advance

of formal submission of their plan for the audit of the MHRA's 2021/22 financial statements at the Committee's next meeting. We have asked Finance to provide a summary of the main accounting policies and likely disclosures required at the year-end arising from the change in Agency status for our January meeting.

Internal Audit

5.11 We received one completed Internal Audit report which assessed the MHRA response to the COVID-19 pandemic and how it was implementing lessons learned to ensure the resilience of the Agency in the event of another major incident. Internal Audit's conclusions are positive, and they awarded moderate assurance. They had only main recommendation which is to provide more detail in the Agency's incident management plan drawing on the experience of responding to COVID-19. We were assured that this is now being done.

5.12 Absence due to illness meant that some other reports were delayed. These are: cash management; implementing the recommendations of the Medical Devices Review; Safety Connect; and Organisation Culture. Work on these is well advanced and we received a verbal update on each. At this point there are no substantial issues to bring to the Board's attention. We were given assurance that the completed reports will be available for our next meeting and that the remainder of the work programme for 2021/22 is sufficiently advanced so that the Head of Internal Audit should be able to provide her annual assurance to the Accounting Officer in May.

5.13 The Agency has enhanced its tracking and reporting of the implementation of audit recommendations. There are currently 77 recommendations reported of which 46 have been implemented, with the remainder dependent on or associated with the Agency's change programme and will be implemented as part of this. Each year Internal Audit highlight wider management systemic issues arising from its work. We asked Internal Audit to update the Committee on their assessment as to the extent of progress in addressing these as part of its annual report.

5.14 Internal Audit provided a helpful summary of issues and good practice arising from its work across government including sources of good practice.

Annual Report-Lessons learned

5.15 We considered a report prepared by the Agency drawing on the advice of external audit which identifies lessons learned from the preparation of the 2020/21 Annual Report and financial statements. The key lesson is the importance of agreeing a detailed timetable with milestones and clear responsibilities assigned early enough. The transition to non-trading fund status increases complexity and it will be important that there are clearly demarcated plans for preparing the final financial statements as a trading fund and for preparing the first set of financial returns to the Department of Health and Social Care for quarter one of 2022/23 as both will consume resources in the same time period. It is also important that one person has overall responsibility for the preparation of the Annual Report and integrating the various contributions into a seamless document.

5.16 The Annual Report is essentially in the first instance an accountability document presented to Parliament and we suggested that ownership might be with the Agency's Governance Office. Communications advice and professional expertise would still be very important once the substantive draft is prepared and agreed.

5.17 The Committee will consider the timetable for preparation of the 2022/23 Annual Report alongside our review of the external audit plan at our January meeting.

Michael Whitehouse
Chair
ARAC
November 2021