Medicines & Healthcare products Regulatory Agency

AGENDA FOR BOARD MEETING HELD IN PUBLIC

10:00 – 12:30 on Tuesday 15 June 2021

Chair: Stephen Lightfoot

	AGENDA ITEM	PURPOSE	PRESENTER
10:00	INTRODUCTION		
	1. What are the priorities for this meeting and how will the meeting run?	Information	Chair
	2. Are there any Apologies or new Declarations of Interest?	Information	All
	3. What were the minutes and actions from the last meeting?	Approval	Chair
10:10	FINANCIAL SUSTAINABILITY		
	4. What were the financial results of the MHRA in 2020/21?	Approval	Jon Fundrey and Michael Whitehouse
10:30	GOVERNANCE		
	5. How well does the draft text of the Annual Report reflect the performance of the MHRA in 2020/21?	Approval	Rachel Bosworth and Michael Whitehouse
10:50	CURRENT CONTEXT		
	6. What are the current key issues from the CEO's point of view?	Discussion	June Raine
11:15	HEALTHCARE ACCESS		
	7. What are the strategic priorities for the development of the Innovative Licencing & Access Pathway?	Discussion	Sam Atkinson
11:40	PATIENT SAFETY		
	8. What assurance can be provided by the Patient Safety & Engagement Committee?	Assurance	Mercy Jeyasingham
12:00	EXTERNAL PERSPECTIVE		
	9. What questions do members of the public have for the MHRA Board?	-	Chair
12:30	CLOSE OF MEETING	-	Chair

Medicines and Healthcare products Regulatory Agency

Minutes of the Board Meeting Held in Public of 18th May 2021

(10:00 – 12:30)

By Zoom Webinar

Present:

The Board

Stephen Lightfoot	Chair
Professor David Webb CBE	Deputy Chair
Dr June Raine CBE	Chief Executive
Dr Barbara Bannister MBE	Non-Executive Director
Amanda Calvert	Non-Executive Director
Professor Bruce Campbell	Non-Executive Director
Jon Fundrey	Chief Operating Officer
Mercy Jeyasingham MBE	Non-Executive Director
John Quinn	Interim Chief Technology Officer
Anne-Toni Rodgers	Non-Executive Director
Dr Christian Schneider	Interim Chief Science Officer
Michael Whitehouse OBE	Non-Executive Director

Others in attendance

Carly McGurry	Director of Governance
Rachel Bosworth	Director of Communications
[redacted]	Secretary to the Board and Head of Directorate
	Executive Assistant to the Chair

Government Legal Department (GLD)

Leah Pickup	Senior Lawyer, MHRA, Medicines and Pharmacy Team, DHSC Legal Advisers, GLD

Department of Health and Social Care (DHSC)

Kathryn Glover	Deputy director, Medicines Regulation and Prescribing, DHSC

Devolved Administrations

Cathy Harrison	Chief Pharmaceutical Officer for Northern Ireland
Professor Alison Strath	Interim Chief Pharmaceutical Officer for Scotland

Item 1: Introduction

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

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

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

Item 2: Are there any Apologies or Declarations of Interest

2.1 Apologies were received from Greig Chalmers, Head of Medicines Policy Branch at the Scottish Government, and Fleur Ruda, Deputy Director of the MHRA, Medicines & Pharmacy division at Government Legal Department.

2.2 Professor Bruce Campbell announced two Declarations of Interest. The first personal specific interest related to advice on generation and publication of evidence for an ultrasound system for renal arteries to detect hypertension for a company called Saluda Medical. The second personal specific interest related to advice provided in relation to a FibroScan device which is used to assess liver fibrosis and cirrhosis through a company called International Innovation House. The Chair noted these Declarations of Interest.

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

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

CURRENT CONTEXT

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

4.1 Dr June Raine presented the Chief Executive's monthly report, which covered topics within the four strategic priorities: (i) healthcare access – including updates on Covid-19 vaccines and batch testing; Covid-19 therapeutics clinical trials; test and trace; use of UK plasmas for manufacture of immunoglobulins; innovative medicines; and the British Pharmacopoeia and Laboratory Services; (ii) partnerships national and international – including updates on collaboration with the Health Research Authority; the International Coalition of Medicines Regularly Authorities (ICMRA); and NIBSC involvement in research into SARS-CoV-2 variants (iii) patient safety – including updates on Covid-19 vaccines and adverse drug reaction reports; parenteral and enteral nutrition bags; the Valproate Stakeholder Network, the Independent Medicines and Medical Devices Safety Review Patient Reference Group; patient involvement for devices clinical investigations; and medicines safety issues; (iv) dynamic organisation – including updates on the Agency transformation strategy; staff engagement with the Delivery Plan 2021-22; Performance Development; a People Survey update; and information on return to work sites; and (v) financial sustainability – including updates on the Agency three-year Business Case; and funding for synthetic data generation.

4.2 Dr Raine highlighted that Dr Alison Cave has been announced as the new Chief Safety Officer; this is a key appointment in the strengthened Agency leadership and governance structure. Dr Raine also highlighted that the MHRA's Drug Safety Update (DSU) bulletin, has retained the NICE accreditation quality standard for another five years. The NICE Accreditation Programme recognises organisations which demonstrate high standards in the production of health or social care guidance. An action was taken to promote the NICE accreditation of DSU in the Agency's communication activities.

4.3 The Board thanked Dr Raine for her report and noted the impressive breadth and depth of activities across the Agency. The Board provided comments on the report regarding ensuring feedback from the patient involvement pilot for devices clinical investigations and clinical trials to the patient and public engagement team; how the NICE accreditation is highly valued and demonstrates how the Agency uses the perspectives of patient and lay representatives; ensuring proactive approaches to devices clinical investigations and to clinical trials; the Agency's work as a key member of ICMRA; the work being undertaken to join the ICH and IMDRF as a standalone member following EU Exit; issues relating to data access; the Agency's ongoing work in low- and middle-income countries to upskill and support the Agency's counterparts in drug safety activities – it was noted an update on the Agency's International Strategy is due to come to the Board shortly. The Board noted Dr Raine's report with thanks.

Action 36: Promote the NICE accreditation of the MHRA Drug Safety Update
Rachel Bosworth

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

5.1 The Board reviewed the Balanced Scorecard, which now has a set of 29 metrics which have been approved by the Executive Committee. Currently 17 of these include live data with a further 12 to be updated later. It was noted that the draft Key Performance Indicators (KPIs) from the Moments of Value workshops were considered, and Scorecard KPIs were compared against the Delivery Plan (DP). While not all DP individual deliverables have a corresponding scorecard measure, the overall suite of KPIs on the scorecard in their entirety reflect the Agency's key strategic priorities.

5.2 The Board endorsed the Balanced Scorecard and agreed that from this point it should be used to measure the Agency's performance. The Board provided further comments regarding how this should be linked to the Corporate Risk Register; and requested that further consideration for future iterations be given to outcomes from safety reports, impact of patient involvement, numbers of novel products or clinical trials being assessed, impact of publications, impact of transformation on operation of the Agency and effectiveness of IT investment.

Action 37: Start using Balanced Scorecard to measure agency performance and consider:

- ***Link with Corp Risk Register***
- ***Outcomes from safety reports***
- ***Impact of patient involvement***
- ***Novel products / clinical trials***
- ***Impact of publications***
- ***Impact of transformation on operation of agency***
- ***Effectiveness of IT investment***

Jon Fundrey

SCIENTIFIC INNOVATION

Item 6: How can we build on the Combined Ways of Working with the Health Research Authority to accelerate the approval of clinical trials?

6.1 The Board considered a paper which described how the Agency can build on the Combined Ways of Working (CWOW) project, working with the Health Research

Authority (HRA), to accelerate the approval of clinical trials. The benefits of a cross-UK and cross-research-ecosystem collaboration, as seen in the UK's response to the Covid-19 pandemic, will be embedded in the Agency's operations moving forward. The Board noted that collaborative working with the HRA is the first step towards realisation of this goal. The Board reviewed the evolution of CWOW, the progress made to date, and the proposed future ambitions and opportunities.

6.2 The Board agreed this is an ambitious programme but is one which clearly links with the Delivery Plan and the broader Governmental priorities around research in the UK. The Board provided further comments covering the need for risk proportionality in clinical trial approval; combination products and innovative products; the importance of encouraging innovative trials designs which could be a USP for the MHRA; enabling multi-site studies and academic trials; ensuring CPRD is properly utilised as a source of real world data; how to streamline ethics approvals; how to bring the National Institute of Health Research into this work; and ensuring that this work can apply across the whole of the UK by taking into account the Northern Ireland Protocol. MHRA will work proactively with DHSC to facilitate this work. The Board agreed this is a vital strategy initiative for UK plc.

PATIENT SAFETY

Item 7: How is SafetyConnect going to improve the safety monitoring of all medical products?

7.1 The Board considered a paper describing the work of the SafetyConnect Programme which is delivering one of the Agency's key objectives to have a more responsive safety surveillance system for all medical products, to keep patients safe. The Board noted that SafetyConnect is making a range of changes to improve how we monitor safety, including: (i) enhancing how patients report suspected adverse incidents and how we engage and provide feedback; (ii) introducing new cutting-edge technology for all our incident management and signal detection work by utilising automation and machine learning; and (iii) creating a new world leading vigilance service by introducing common ways of working across all vigilance activities and medical products.

7.2 The Board considered the work of the SafetyConnect programme and noted the project is focusing on three key areas: patients, performance and partnerships. SafetyConnect draws together a diverse series of ambitious changes in a complex area to achieve its goals. The Board commented that this programme has a clear set of deliverables with strong patient engagement throughout and is clearly linked with the Delivery Plan.

7.3 The Board also supported the suggestion that there should also be a 'person on the end of the phone' available to patients as an alternative to electronic reporting. It was confirmed this is already possible via the Customer Service Centre; enabling a two-way discussion with patients and the public. Other comments included increasing public awareness of the MHRA and the Yellow Card Scheme; how to build partnerships and wider relationships with external stakeholders and how to establish system-wide governance for oversight; how appropriate governance will be vital to the success of this programme; how to consider appropriate branding; and ensuring data standards and safety of data.

7.4 The Board commented that the PSEC and ARAC should agree how to provide assurance to the Board on the development, governance and data standards of SafetyConnect. The Board were assured by this report of the SafetyConnect programme and thanked all who have worked to bring this programme to this stage.

Action 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

COLLABORATIVE PARTNERSHIPS

Item 8: What are the communication priorities to build public and stakeholder trust in the MHRA?

8.1 The Board considered a high-level communications strategy for the Agency, with proposals for communication priorities to build and enhance trust with each of our key target audiences, including patients, public, healthcare professionals, industry, government, staff, NHS and the media. The Board agreed that this is an ambitious strategy to change the way the Agency communicates with its key stakeholders. It will also involve all staff having a communications objective that will enable staff throughout the Agency to own the agency's reputation and engagement with stakeholders.

8.2 The Board provided comments regarding the importance of two-way engagement with patients and the public; how to prevent MHRA messages competing with other health agencies; collaboration with NICE on guidance; avoidance of alert fatigue; improving engagement with the general public; proactive rather than reactive engagement; and ensuring that public trust and confidence in the independence and objectivity of the MHRA is maintained. The Board endorsed the strategy and priorities.

Action 39: Implement the Communications Strategy with particular focus on measuring trust and communications with healthcare professionals.

Rachel Bosworth

FINANCIAL SUSTAINABILITY

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

9.1 The Board considered an assurance report from the Audit and Risk Assurance Committee (ARAC) which addressed two actions assigned to the ARAC at the February 2021 Board meeting, and a summary of the key outcomes of the April 2021 ARAC meeting. The Board queried the accounting error regarding VAT charges on CPRD sales which was not picked up internally or by external auditors and asked for assurance that this would not recur. The Board were assured that an error like this would not be repeated due to the Finance Transformation work, the updated VAT guidance for the Agency, and the appointment of a Tax & Compliance Officer.

9.2 The Board noted the report and agreed to the proposed more detailed "Deep Dive" reviews by ARAC together with the Patient Safety and Engagement Committee into: (i) the new Medical Devices Regulatory Framework as it is finalised specifically from the perspective of managing risks to patient safety; and (ii) how the data and evidence sources of the Agency are changing and how the Agency is ensuring it has access to the information it needs to discharge its responsibilities.

Action 21: ARAC to review governance and risks of the new medical devices regulatory framework.

Michael Whitehouse / Mercy Jeyasingham

EXTERNAL PERSPECTIVE

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

9.1 The Board answered a range of questions from members of the public. There were questions relating to Covid-19 vaccines, Covid-19 testing, patient involvement in clinical trials, the Yellow Card Scheme, trial design and ethics approvals, drug safety in low- and middle-income countries, the Agency's international strategy, and isotretinoin. An action was taken to update the MHRA website with dates of the Isotretinoin Expert Working Group (EWG) patient engagement sessions.

Action 40: Update the MHRA website with dates of the Isotretinoin EWG patient engagement sessions.

Rachel Bosworth

SUMMARY OF ACTIONS FROM MHRA BOARD MEETING IN PUBLIC – 18 May 2021

Action Number	Action	Owner	Date	Status
Carried Forward from previous meetings				
15	Review Agency Fee structure to ensure closer alignment with costs of delivery	Jon Fundrey	15/06/21	Verbal update
21	ARAC to review governance and risks of the new medical devices regulatory framework	ARAC	~~18/05/21~~ 20/07/21	Joint review of the framework to be undertaken by ARAC and PSEC
22	Present an update to the Board on how the short, medium and long-term deliverables from IMMDSR are being measured over time.	June Raine	20/07/21	
23	Review the operations, financial model, strategic outcomes and stakeholder feedback on ILAP	Sam Atkinson	~~18/05/21~~ 15/06/21	On agenda
27	ODRC to review Diversity and Inclusion to provide assurance to the Board	ODRC	~~20/04/21~~ ~~15/06/21~~ 20/07/21	
29	Present an Agency Laboratory Strategy to the Board as part of the Agency Science Strategy.	Christian Schneider	21/09/21	
33	Consult members of the public on the branding of the Yellow Card Biobank.	Chief Safety Officer	21/09/21	
34	The MHRA had a commitment in the Life Sciences Sector Deal 2 to publish a new regulatory pathway for genomic medicines and genomic tests by March 2021. Provide an update on progress of this commitment.	June Raine	~~18/05/21~~ 21/09/21	
New Actions				
36	Promote the NICE accreditation of the MHRA Drug Safety Update	Rachel Bosworth	15/06/21	Verbal Update
37	Start using Balanced Scorecard to measure agency performance and consider: - link with Corp Risk Register - outcomes from safety reports - impact of patient involvement - novel products / clinical trials - impact of publications - impact of transformation on operation of agency - effectiveness of IT investment	Jon Fundrey	15/06/21	Verbal Update
38	PSEC and ARAC to agree how to provide assurance to the	Mercy Jeyasingham	20/07/21	

	Board on the development, governance and data standards of SafetyConnect	and Michael Whitehouse		
39	Implement the Communications Strategy with particular focus on measuring trust and communications with HCPs	Rachel Bosworth	16/11/21	
40	Update the MHRA website with dates of the Isotretinoin EWG patient engagement sessions	Rachel Bosworth	15/06/21	Verbal Update

Medicines & Healthcare products Regulatory Agency

BOARD MEETING HELD IN PUBLIC

15 June 2021

Title	What were the financial results of the MHRA in 2020/21?
Board Sponsor	Jon Fundrey Chief Operating Officer
Purpose of Paper	Approval

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

1. Executive Summary

1.1 The paper sets out the MHRA financial performance in 2020/21 as set out in the draft 2020/21 Annual report and Accounts [unaudited].

1.2 The Board is asked to note the Agency's financial performance and outturn for the last financial year and consider the implications for the current financial year.

2. Financial Review 2020/21 (unaudited)

2.1 The Agency's financial performance in 2020/21 reflects the continued change in the Agency's sources of funding and revenue after the UK's exit from the European Union. In this financial year the agency's performance has also been impacted by the pandemic.

2.2 As a Trading Fund the Agency is required by a HM Treasury Minute to achieve a return averaged over the five-year period from 1 April 2018 to 31 March 2023 of at least 3.5% in the form of an operating surplus on ordinary activities before interest and dividends expressed as a percentage of average capital employed. Capital employed consists of the Agency's capital and reserves.

2.3 The Agency is funded mostly by income from fees for both statutory and non-statutory sales of products and services. Income from fee-generating activities in 2019/20 was £96.5m which was £8m lower than in 2019/20. The decline in revenues reflected primarily a reduction in the level of annual service fee, and lower non-statutory sales at NIBSC as focus and capacity during the year was diverted onto the COVID-19 effort, leading to deferral of work in other areas. Income from research activities in 2020/21 also decreased from last year. As in the preceding financial year, the Agency received EU Exit transition funding from DHSC, which amounted to £12.8m in 2020/21 - broadly comparable to that received in 2019/20 of £12.6m. Consequently the 2020/21 total trading income of £146.5m was £8.2m lower than that in 2019/20.

2.4 Staff costs increased by £6.2m (7.2%) reflecting mainly a 7.5% increase in the average number of employees, both permanently and temporarily employed, the latter primarily to increase capacity for peak workload during EU Exit transition and for the COVID-19 effort. Also contributing to the increase was a Civil Service pay settlement of 2.5%. Operating costs increased by £2.5m from last year. A £3.4m increase in computing costs in 2020/21 and a further £1.6m increase in depreciation and amortisation has been partially offset by lower accommodation and travel and subsistence costs, the latter heavily impacted by the national lockdowns and travel restrictions, which prevailed through most of the year.

2.5 The resulting 2020/21 operating surplus before interest and dividends was £0.5m compared to £16.9m in 2019/20. The reduction in surplus in 2020/21 was a combination of lower revenue (£7.7m) and higher costs (£8.7m).Total comprehensive income for the year was a loss of £3.9m after a £4.1m revaluation loss on land and buildings at the South Mimms site, which reversed some of the revaluation gain recorded in 2019/20.

2.6 After dividends payable of £15.3m a net deficit of £14.8m was transferred to reserves.

2.7 2020/21 has seen a net cash outflow from operating activities of £2.95m compared to £16.3m inflow in 2019/20. The current year operating cash outflow was driven by the small operating surplus of £0.5m adjusted for non-cash items (add back depreciation of £10.3m; less DHSC non-cash funding of £12.4m) along with a £1.3m cash outflow from an increase in working capital.

2.8 Cash for purchases of tangible and intangible assets was a further outflow of £4m and there was a net cash outflow of £2.7m from financing activities, mainly the payment of a cash dividend to DHSC. As a result, cash and cash equivalents at the end of 2020/21 financial year were £9.7m lower than at the end of 2019/20.

3. Recommendation

3.1 The Board is asked to approve the financial outturn for the 2020/21 financial year, subject to final audit sign-off.

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

Jon Fundrey
8 June 2021

EXTRACT FROM DRAFT 2020/21 ANNUAL REPORT AND ACCOUNTS

Summary of comprehensive income for the year ended 31 March 2021 (*unaudited*)

	2020/21		2019/20	
	£000	**£000**	£000	£000
Income				
Trading Income				
Income from marketing authorisations	**26,514**		24,710	
Income from clinical trials	**3,576**		3,323	
Income from research activities	**2,416**		3,362	
Income from other trading activities	**70,704**		79,899	
Income from Department of Health and Social Care	**43,336**		43,450	
Total Trading Income		**146,546**		154,744
Other income		**12,434**		11,953
Total income		**158,980**		166,697
Expenditure				
Staff costs	**(92,439)**		(86,224)	
Operating costs	**(66,044)**		(63,569)	
Total Expenditure		**(158,483)**		(149,793)
Operating Surplus		**497**		16,904
Finance income		**6**		584
Finance costs		**(47)**		(47)
Surplus for the financial year		**456**		17,441
Other comprehensive income				
Realised loss on inventories		**(188)**		(89)
Net (loss)/gain on revaluation of property, plant and equipment*		**(4,138)**		7,266
Total comprehensive income for the year		**(3,870)**		24,618

*All gains and losses arise from continuing operations.

Summary of financial position as at 31 March 2021 (*unaudited*)

	31 March 2021		31 March 2020	
	£000	**£000**	£000	£000
Non-current assets				
Property, plant and equipment	**128,122**		137,789	
Intangible assets	**13,389**		14,235	
Trade and other receivables	**7,291**		7,753	
Total non-current assets		**148,802**		159.777
Current assets				
Inventories	**9,563**		5,838	
Contract assets	**6,948**		6,611	
Trade and other receivables	**37,003**		27,475	
Cash and cash equivalents	**79,601**		89,285	
Total current assets		**133,115**		129,209
Total assets		**281,917**		288,986
Current liabilities				
Contract liabilities	**(12,761)**		(11,124)	
Trade and other payables	**(42,701)**		(34,458)	
Other liabilities	**(14,135)**		(15,044)	
Provisions	**(1,781)**		-	
Total current liabilities		**(71,378)**		(60,626)
Total assets less current liabilities		**210,539**		228,360
Non-current liabilities				
Contract liabilities	**(4,574)**		(3,555)	
Other liabilities	**(28)**		(25)	
Provisions	**(1,998)**		(1,711)	
Borrowings	**(1,328)**		(1,328)	
Total non-current liabilities		**(7,928)**		(6,619)
Assets less liabilities		**202,611**		221,741
Taxpayers equity				
Public dividend capital		**1,329**		1,329
Reserves				
Revaluation reserve		**110,829**		115,155
Income and expenditure reserve		**954**		954
General fund		**89,499**		104,303
Total equity		**202,611**		221,741

Summary of cash flows for the year ended 31 March 2021 (*unaudited*)

	2020/21		2019/20	
	£000	**£000**	£000	£000
Cash flows from Operating activities				
Operating surplus	**497**		16,904	
Depreciation and amortisation	**10,338**		8,754	
Loss on disposal of assets	**22**		5	
Impairment of property, plant and intangible assets	**18**		261	
Realised loss on inventories	**(188)**		(89)	
(Increase) in inventories	**(3,725)**		(171)	
(Increase) in Contract assets	**(337)**		(19)	
Increase/(Decrease) in Contract liabilities	**2,656**		(548)	
(Increase)/Decrease in trade and other receivables	**(9,066)**		1,039	
(Decrease) in trade and other payables	**(4,330)**		(10,942)	
(Decrease) in other liabilities	**(906)**		(281)	
Increase in provisions	**2,068**		1,390	
Net cash (outflow)/inflow from operating activities		**(2,953)**		16,303
Cash flows from investing activities				
Purchase of property, plant & equipment	**(2,214)**		(1,529)	
Purchase of intangible assets	**(1,789)**		(3,768)	
Net cash (outflow) from investing activities		**(4,003)**		(5,297)
Cash flows from financing activities				
Interest received		**6**		584
Interest paid		**(47)**		(47)
Dividend paid		**(2,687)**		(2,196)
Net cash (outflow) from financing		**(2,728)**		(1,659)
Net (decrease)/increase in cash and cash equivalents in the financial year		**(9,684)**		9,347
Cash and cash equivalents at the beginning of the financial year		**89,285**		79,938
Cash and cash equivalents at the end of the financial year		**79,601**		89,285

Summary of changes in taxpayer's equity for the year ended 31 March 2021 (*unaudited*)

	PDC	General Fund	Reval. reserve	I & E reserve	Total
	£000	£000	£000	£000	£000
Balance at 31 March 2019	**1,329**	**101,500**	**107,978**	**954**	**211,761**
Changes in taxpayer's equity for 2019/20					
Surplus for the year	-	17,441	-	-	17,441
Other changes					
Net loss on revaluation of property, plant and equipment	-	-	7,266	-	7,266
Realised loss on inventories - biological standards	-	-	(89)	-	(89)
Dividend payable	-	(14,638)	-	-	(14,638)
Sub total	-	(14,638)	7,177	-	(7,461)
Balance at 31 March 2020	**1,329**	**104,303**	**115,155**	**954**	**221,741**
Changes in taxpayer's equity for 2020/21					
Surplus for the year	-	456	-	-	456
Other changes					
Net loss on revaluation of property, plant and equipment	-	-	(4,138)	-	(4,138)
Realised gain on inventories - biological standards	-	-	(188)	-	(188)
Dividend payable	-	(15,260)	-	-	(15,260)
Sub total	-	(15,260)	(4,326)	-	(19,586)
Balance at 31 March 2021	**1,329**	**89,499**	**110,829**	**954**	**202,611**

Medicines & Healthcare products Regulatory Agency

BOARD MEETING HELD IN PUBLIC

15 June 2021

Title	How well does the draft text of the Annual Report reflect the performance of the MHRA in 2020/21
Executive Sponsor	Rachel Bosworth Director of Communications
Purpose of Paper	Approval

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

1. Executive Summary

1.1 The Agency's Annual Report and Accounts give an overview of the Agency's work and key events that had the most impact during the 2020/21 financial year. It also outlines the work undertaken by the Agency to deliver on its corporate plan. The draft text contains substantive contributions from all parts of the Agency and has been reviewed and edited to include recommendations from the Executive Committee and the Audit and Risk Assurance Committee. The Board is asked to consider how well the draft text of the Annual Report reflects the performance of the MHRA in 2020/21 and advise whether any changes or additions should be made. The Annual Report and Accounts 2020/21 will be laid before Parliament by 30 June 2021.

2. Content

2.1 The Annual Report follows a prescribed format, defined by Government, which includes the following:

Forewords from the Chair and Chief Executive setting out their overview of the year.

Performance report - this provides information on the Agency's main objectives and strategies as well as the principal risks faced during the year.

Performance overview and analysis - this section provides a summary with sufficient information to understand the organisation, its purpose, the key risks to the achievement of its objectives and how it has performed during the year. The draft text includes information on the Agency's response to the COVID-19 pandemic, the Independent Medicines and Medical Devices Safety Review (IMMDSR), and EU exit. It also outlines the Agency's work in protecting public health, regulation and setting standards.

Accountability report – this section's purpose is to meet key accountability requirements to Parliament.

Corporate governance report – this section explains the composition of the organisation, the governance structures and how they support the achievement of the Agency's objectives. The draft text includes information about the governance changes that occurred during 2020/21.

Remuneration and staff report – this section sets out the Agency's remuneration policy for directors and senior managers, reports on how that policy has been implemented and sets out the amounts awarded to directors and where relevant the link between performance and remuneration.

Parliamentary accountability and audit report and financial statements – this section includes the audit report and the Agency's financial statements for the 2020/21 financial year.

2.2 The Annual Report and Accounts needs to be laid before Parliament no later than 30 June, in line with HM Treasury direction. Ministerial clearance on the draft will be sought before publication.

3. Recommendation

3.1 The Board is asked to consider how well the draft text of the Annual Report reflects the performance of the MHRA in 2020/21 and advise whether any changes or additions should be made.

Rachel Bosworth
15 June 2021

Medicines & Healthcare products Regulatory Agency

BOARD MEETING HELD IN PUBLIC

15 June 2021

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

Chief Executive's Report to the Board
June 2021

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

EXECUTIVE SUMMARY 'TOP 10' HEADLINES

- The Janssen-Cilag single dose COVID-19 vaccine was approved, the fourth UK approval
- The Pfizer/BioNTech COVID-19 vaccine has been approved in children aged 12-15 years following a rigorous review of clinical trials in over 2,000 children
- NIBSC completed the testing and certification in May of 15 batches of 3 different COVID-19 vaccines, equating to over 14m doses allocated to the UK vaccination programme
- The first MHRA product approval under Project Orbis was issued for a treatment for lung cancer post-surgery (Tagrisso, osimertinib), several months ahead of the usual timeframes
- With partners at NICE, CQC and HRA we announced a Multi-Agency Advisory Service for AI and digital technologies to reduce the time for these innovations to reach healthcare
- Analyses by NIBSC with Imperial College, PHE and Covid-19 Genomics UK have shown the COVID-19 delta variant is now over 50% of the virus sequences in London sewage
- Over 889,000 medical devices on the GB market have now been registered by MHRA in an initiative which will enable strengthened device safety monitoring
- The Yellow Card App has now been integrated into the NHS App to make reporting easier
- During Operation Pangea the Enforcement team seized millions of illegal medical products at UK points of entry, and coordinated the arrests of several suspected organised criminals
- We contributed to the G7 Health summit session on vaccine confidence and supported the development of proposals on international Clinical Trials collaboration.

HEALTHCARE ACCESS

COVID-19 vaccines

1. The Janssen-Cilag single-dose COVID-19 vaccine was approved under the new EU 'Reliance' procedure and doses are expected to be available for UK deployment later this year. Following careful assessment of clinical trial data in children aged 12 to 15 years the Agency concluded that the Pfizer/BioNTech Covid-19 vaccine is safe and effective in this age group and that the benefits of the vaccine in adolescents outweigh any risk. We have put in place a comprehensive surveillance strategy for monitoring the safety of all UK-approved COVID-19 vaccines and this surveillance will include the 12 to 15-years age group. The JCVI will now advise on whether this age group will be vaccinated as part of the UK deployment programme. We continue to provide scientific advice to companies proposing to introduce vaccines adapted to COVID-19 variants.

COVID-19 vaccine independent testing by NIBSC

2. During May 2021, NIBSC completed the testing and certification of 15 batches of three different COVID-19 vaccines. This equates to over 14 million doses allocated to the UK vaccination programme. In total, since the start of batch testing in December 2020, 85 batches of vaccines have been tested and certificated which is the equivalent of more than 82 million doses.

Rapid C-19 Oversight group

3. The MHRA has been an active participant of the Rapid-C19 oversight group together with NHSE&I, NICE, DHSC, NIHR and Health technology assessment representatives from the devolved nations, agreeing Rapid Action Plans for COVID-19 therapeutics in development, including patient access. In May the Group reached a milestone of 50 meetings providing recommendations to the Chief Medical Officer on several COVID-19 treatments including dexamethasone, remdesivir, budesonide and tocilizumab.

Novel Polio vaccine

4. NIBSC's WHO Collaborating Centre for Polio, together with the Centers for Disease Control and Prevention in Atlanta USA, is supporting the implementation phase of the novel type 2 oral polio vaccine (nOPV2) under WHO's Emergency Use Listing with a view to achieving full licensure in the next few years. Testing of nOPV2 isolates from vaccination campaigns in Africa started in May 2021 to evaluate the genetic stability and safety of the vaccine. A paper on nOPV2 by NIBSC was discussed on TV on a recent episode of This Week in Virology (TWiV) (https://www.microbe.tv/twiv/twiv-756/).

Innovative Licensing and Access Pathway

5. The Innovative Licensing and Access Pathway (ILAP) has now received 32 applications for the Innovation Passport from a variety of sponsors including large and small companies and in common diseases as well as rare diseases. Of the first 25 Innovation Passport applications, 8 have expressed interest in entering Project Orbis. The first Innovation Passport was awarded at the end of February to Belzutifan, a treatment developed by MSD (UK) for adults with von Hippel Lindau disease. We have now received one request for a Target Development Profile. We have set up a dedicated ILAP patient reference group with 16 representatives who will contribute to the decision making for the Innovation Passport designation.

Clinical Trials strategy

6. The Clinical Trials Unit (CTU) has supported a number of objectives in the Recovery, Resilience and Growth (RRG) Programme set up by DHSC to support UK clinical research. The Clinical Trials Unit and representatives from the MHRA Good Clinical Practice (GCP) Inspectorate recently participated in the first meeting of a Guidance Task and Finish group, and also joined a new Remote Trial Delivery Group which aims to promote guidance for remote clinical trials and to ensure that current resources are utilised appropriately. The outcomes of the group's work will also aim to increase research participation in under-served groups, which links to the RRG commitment to increase diversity in studies, a joint project between MHRA and the Health Research Authority (HRA).

PARTNERSHIPS NATIONAL AND INTERNATIONAL

Multi-Agency Advisory Service

7. On 18 May, along with partners at NICE, the Care Quality Commission, and the Health Research Authority, we announced the development of the Multi-Agency Advisory Service (MAAS). The precise design of the service will be decided via a user needs approach, but overall the Service will make the process for developing and adopting artificial intelligence and data-driven technologies in healthcare clearer and more contiguous. The MAAS has already begun work to ensure there are no gaps in

regulation between the partner agencies, to identify opportunities to align requirements, and ideally to hide any remaining complexity from the market. In short, MAAS seeks to minimise unnecessary burdens on healthcare access via inter-agency collaboration, thereby ensuring that developers no longer must embark upon a 'regulatory odyssey' to bring their data-driven products to market.

Collaboration with Singapore Health Sciences Authority

8. During May the Defective Medicines Report Centre met the Singapore Health Sciences Authority (HSA) as a part of an information sharing initiative relating to quality defects. This initiative has proved to be a vital forum for sharing information and learning post-EU Exit and also due to the increased number of quality defects occurring globally. The meeting was an opportunity to discuss how both regulators work to actively investigate and find suitable solutions to the issues that arise without causing unnecessary public concern. The meeting received good feedback and HSA valued the MHRA contribution. We also learned more about the HSA systems and tools and this has benefitted our practice. This network will continue to be useful and further training and information sharing is planned, along with ad-hoc discussions on global safety issues.

International regulatory collaboration

9. The MHRA is now a full partner in the ACCESS Consortium (a coalition of the regulatory authorities for Australia, Canada, Switzerland, Singapore and UK). Guidance documents have been published including information on the work-sharing initiatives for New Active Substances and Generic Medicines. The recent Heads of Agencies meeting held in May 2021 discussed the future strategic plan of the consortium, alongside progress updates for the various ACCESS working groups. Three industry Expression of Interest forms have been received for the New Active Substance Work Sharing that includes MHRA, with the first application due to be submitted at the end of June 2021. The COVID-19 Vaccines and Therapeutics Working Group has published guidance for authorised vaccines on strain changes and we regularly participate in meetings of the Information Technology Working Group and the International Committee on Harmonisation Working Group of ACCESS Coordinators.

FDA Project Orbis

10. The MHRA is now a full participant in Project Orbis, a programme coordinated by the US Food and Drug Administration (FDA) to review and approve promising cancer treatments. It involves the regulatory authorities of Australia, Canada, United Kingdom, Singapore, Switzerland and Brazil, and provides a framework for concurrent submission and review of oncology products among international partners. A post-surgery treatment for lung cancer, osimertinib (Tagrisso), was the first product to receive an authorisation from MHRA under Project Orbis, and this will shorten the time to reach patients by several months compared with the EU process.

Clinical Trials Workshop with the Chinese National Medical Products Administration

11. In May the MHRA Clinical Trials Unit held the second workshop with colleagues from the Chinese National Medical Products Administration (NMPA). This workshop focussed on the assessment of First in Human trials. Attendance from NMPA assessors included at least 60 staff who attended onsite, and more joined online. The workshop was well received, with the content matching NMPA's learning objectives. The Q&A sessions and panel discussions were also well received, with high levels of engagement. The feedback was very positive and NMPA would like to continue collaboration in the future. A senior level bilateral meeting will take place in June.

Collaboration with WHO for pharmacopoeial monographs for Favipiravir

12. The World Health Organisation's (WHO) International Meeting of World Pharmacopoeias (IMWP), of which the British Pharmacopoeia (BP) is an active member, has published draft IMWP monographs for Favipiravir and Favipiravir Tablets for public comment. These non-mandatory monographs were developed by the IMWP as a resource to aid independent users in their assurance of medicines quality. This is a result of global collaboration amongst the pharmacopoeias in response to the COVID-19 Pandemic. It should be noted that the development of these monographs does not imply or confer any demonstrated effectiveness of Favipiravir in the treatment of COVID-19, nor does it recommend its therapeutic use.

PATIENT SAFETY

COVID-19 vaccines safety

13. We continue to publish weekly reports of all ADRs received in association with COVID-19 vaccines. While the monitoring of reported cases of thrombosis with low platelets continues, work is ongoing to identify whether there is a causal relationship with COVID-19 vaccines, and if so, what the underlying mechanism is. A working group meets regularly to assess the latest UK and international case information and published literature to identify risk factors and mitigations for high risk groups. At present no causative factors have been identified.

14. Up to 2nd June 2021 there were 27,965 individuals registered with Yellow Card Vaccine Monitor. The MHRA is using the data collected through the Monitor to aid our signal detection activities for COVID-19 vaccines currently in use in the UK. The first stage of work involving Yellow Card integration into the NHS app is now complete. Full vaccination records are now prominently displayed on the home screen together with information about reporting side effects and a link to the Coronavirus Yellow Card reporting site. Through SafetyConnect this will be rolled out to all other products.

COVID-19 Testing

15. The Devices team is working with manufacturers of Lateral Flow Tests and DHSC Test and Trace to provide effective regulatory scrutiny to support a pipeline of safe and performing tests as well as providing post-market surveillance activities for the national programme. The DHSC Test and Trace has been granted an extension to the existing Exceptional Use Authorisation for Lateral Flow Tests based on the repurposed Innova tests for surge and regular testing to find positive cases in asymptomatic populations. Regular conference calls are held with international regulators to share information on all aspects of COVID-19 Testing including the requirements placed on manufacturers to undertake regular assessment of the performance of their assays against new variants. We require fortnightly testing against the information provided in GISAID (GISAID is an initiative which promotes the rapid sharing of data from all influenza viruses and the coronavirus causing COVID-19) with favourable and unfavourable results being reported to us.

Isotretinoin

16. We are now reaching the next milestone in the review of the safety of isotretinoin, a treatment for severe acne, and the psychiatric and sexual side effects suspected to be associated with isotretinoin, which is being carried out by the Commission on Human Medicines (CHM). The CHM's Isotretinoin Expert Working Group (IEWG) is carefully

considering all of the available information submitted during the public consultation earlier this year. To aid the assessment of these important issues, the IEWG is holding a virtual meeting on 16th July 2021 and will invite patients and other stakeholders to attend to present their experiences with isotretinoin and particularly their views on how any the risks associated with isotretinoin could be best managed. The purpose of this meeting is for the IEWG to hear directly from patient, families and other stakeholders, focussing on information that has not already provided through the consultation or reported via the Yellow Card scheme. We contacted patients and stakeholders who had confirmed they would like to be kept informed about the review, to register their interest in attending, and information has been published on the isotretinoin review page on GOV.UK. We also carried out social media activity to promote this.

NIBSC collaborative surveillance of SARS-CoV-2 variants of concern

17. Collaboration is ongoing between NIBSC, Imperial College London, Public Health England (PHE) and Covid-19 Genomics UK consortium (COG-UK) to analyse recent trends in SARS-CoV-2 variants of concern in England, showing that local transmission of non-B.1.1.7 variants of concern is increasing, which warrants urgent further investigation. The study combines the use of passive-case detection PCR data, cross-sectional community infection surveys, genomic surveillance, and wastewater monitoring. NIBSC is responsible for wastewater monitoring having established a method to quantify specific variants in sewage concentrates. This work continues and we now have evidence of the B.1.617.2 variant, first detected in India, making up more than 50% of the virus sequences in London sewage.

Devices Sterilisation service

18. We have contacted manufacturers to alert them to an issue with a third party sterilisation provider Steril Milano who was found to be falsifying sterilisation documents. The risk to patients from the sterilisation issue has been assessed as being very low. There is a potential impact on the global supply chain for some products; the FDA and SwissMedic have issued communications on the topic. The team are working with manufacturers on their Field Safety Notices (FSNs) and with partners across the health and social care system to assess risks, provide access to alternative devices by providing Exceptional Use Authorisations (EUAs) and develop and implement effective safety communications where necessary.

Medical device registration

19. Manufacturers needed to register all active implantable medical devices; Class III medical devices; Class IIb implantable medical devices and IVD List A products on our database by 1 May 2021. In total 521,792 medical devices within these categories were registered in MHRA's system. Manufacturers of all other classes of medical devices have also been able to register in advance of the two further deadlines. In total, 667,332 devices were registered in this period. Together with Class I and other devices registered on the pre-transition version of the Appian database, MHRA now holds registration data for over 889,000 medical devices on the GB market. Future enhancements to the transition registration system would enable more MHRA staff to view all the data and for the public to find out details about medical devices placed on the GB market. Some of this requires further accompanying legislative change.

Operation Pangea

20. This year's global week of action on illicit supply of healthcare products, Operation Pangea, ran from 18th-25th May. MHRA officers proactively seized millions of illegal medicines and medical products at UK points of entry, identified and removed thousands of illegal pharmacy-style websites and URLs, and coordinated the arrests of several suspected organised criminals. With over 100 countries participating, we play a key role on the Pangea steering committee and have delivered unparalleled results in terms of reducing criminal threats and maintaining patient safety. The post-operation phase will involve a detailed analysis of the global data to create a better understanding of current and emerging threats, including 'hotspot' exporting countries, favoured high-risk medicines being traded on the black market, and ever-evolving criminal business models. The sharing of best practice with our partners, together with ongoing collegiate work with major exporter countries such as India, is expected to enhance the capabilities of international stakeholders and ramp-up our ability to tackle criminal activity. The News Team is currently working with Interpol to deliver a national and international media briefing on June 8, raising awareness of threats associated with medical product crime.

DYNAMIC ORGANISATION

Agency Transformation Programme

21. We are actively progressing with the Transformation Programme, making some final adjustments to the proposed structure following the alignment of affordability with the end of year financial position. The finalisation of the Digital, Data and Technology roadmap has enabled us to progress negotiations with potential suppliers. It will enable the Agency to make better use of our existing modern platforms, but take a radically different approach to that of the past which will both reduce the costs of ongoing maintenance and the costs of future change, supporting the Agency's future financial stability, whilst keeping our systems and services running safely and securely.

Health and Safety Reviews

22. On 21st May the Health & Safety (H&S) team underwent a successful ISO 45001 audit. The scope was the H&S management system for the 10SC site, but the audits are helpful to highlight any issues with the overall management of health and safety activities across the organisation. There were no non-conformities and 2 opportunities for improvement. These were in relation to the much reduced completion of CSL mandatory training, which has been impacted by the pandemic but still needs to be completed to avoid a non-conformity at the next audit, and a recommendation to look into root causes and corrective actions in relation to internal audit non-conformities, which was already under review by the H&S Team.

23. On 21st May, NIBSC underwent its Annual Review by the Health & Safety Executive (HSE). Agency senior leaders are the duty-holders for the work with high consequence biological agents that have a major accident hazard potential, and for which NIBSC is automatically given a high hazard inherent scoring. NIBSC was found to be broadly compliant with the requirements under the performance assessment. Minor issues identified at interventions demonstrated that proactive safety performance remains consistent, but there are still improvements to be made to the safety management system and operational standards for work with biological agents.

24. The HSE highlighted that the NIBSC strengths are a continued commitment to H&S and Biocontainment at all levels that ensure the highest level of control and protection to operators. NIBSC has built on previous success and applied this to rapidly developing situations, particularly evident in business continuity during the COVID-19 pandemic. There is a positive outlook and a willingness to learn from interventions and apply this across the organisation, with a transparent approach and attitude during interventions.

FINANCIAL SUSTAINABILITY

Corporate Overheads

25. The Corporate Overheads pathfinder project to define and propose opportunities to reduce corporate costs is making good progress and is expected to report shortly. In addition, we are recruiting fixed term staff to address non-pay overheads with the objectives of reaching target savings and strengthening the Agency's general contract management capability, building on the existing work in this team.

Future Fees Strategy

26. Work is under way to define our future fees strategy. A cross-agency group has been formed and is finalising the scope of the work in relation to our current fees and costs. The scope of the work has been widely drawn to encompass all activities that generate income for the agency (e.g. NIBSC standards) rather than just statutory services. It is expected to take around 12 months to define, consult, legislate and implement a new fees structure for the Agency.

June Raine
7 June 2021

Medicines & Healthcare products Regulatory Agency

BOARD MEETING HELD IN PUBLIC

15 June 2021

Title	What are the strategic priorities for the development of the Innovative Licencing & Access Pathway (ILAP)?
Board Sponsor	Samantha Atkinson Interim Chief Quality & Access Officer
Purpose of Paper	Discussion

What are the strategic priorities for the development of the Innovative Licencing & Access Pathway (ILAP)?

1. Executive Summary

1.1 A new ambitious pathway for accelerating time to market for innovative medicines was launched in the UK in December 2020 and has been open for business since 01 January 2021. The Innovative Licensing and Access Pathway (ILAP) provides a unique framework for enhanced collaboration between the MHRA and the two ILAP partners, the National Institute for Health and Care Excellence (NICE) and the Scottish Medicines Consortium (SMC). The pathway supports expedited, efficient and innovative approaches to the product development programme – including iterative assessments, proactive pharmacovigilance and a whole-lifecycle approach to efficient evidence generation.

1.2 This paper provides an update on the ILAP activity to date and addresses the current and future strategy aspects of the pathway as the principles and operational aspects continue to evolve. The most pressing strategic issues are embedding the patient voice in the ILAP, creating a sustainable model for delivery from a resourcing perspective and finalising the partnership agreements with ILAP partners, which needs to include consideration of the strategic fit across the broader health landscape.

2. Introduction

2.1 The ILAP covers the entire development programme with a clear ambition to speed up the time to patient and market access in an ‘end to end’ approach. The key aspects of the pathway are the medicines designation (Innovation Passport, IP), the road map (Target Development Profile, TDP) and the tool kit.

2.2 **Innovation Passport (IP) Designation**: The first step in the ILAP is the Innovation Passport application. The Innovation Passport is the mandated entry point to the ILAP and is open to developers at the pre-clinical trial stage through to the later development. The entrance criteria for ILAP are broad and inclusive, in order to support a wide range of products and new indications, including repurposed medicines. Companies are encouraged to engage early before they have clinical data (pre-first in human studies) in order that all the benefits of enhanced interactions with the MHRA and the partners can take place. Successful applicants at the IP stage move on to the portfolio activities as part of the creation and implement of a product specific Target Development Profile (TDP).

2.3 **Target Development Profile (TDP)**: A team of experts will help define the target development profile (TDP) 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. The TDP will include details about how to work with other UK stakeholders for coordinated and efficient evidence generation and evaluation, whilst also addressing commercial and managed access considerations. It is expected that the TDP is a living document, updated along the development programme timelines and milestones as new data and evidence are generated. Therefore, there will be multiple TDP versions over time for products that enter the ILAP at an early stage.

2.4 **Toolkit**: The 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. More details of the toolkit can be found here: https://www.gov.uk/guidance/the-target-development-profile-toolkit

2.5 **ILAP activity in the first four months of operation**

- In the first 4 months of operation (January – April 2020) we received 25 new applications for the Innovation Passport and one application for the TDP step. This has exceeded expectations. The total number of applications to date is 32 with significant numbers in line for submission based on discussions with industry.

- There was a good representation of large and small companies, (including a university spinout) and common conditions (e.g. lung cancer, community acquired pneumonia, chronic wounds, diabetes) and rare diseases. Of the 25 IP applications, 8 expressed interest in Project Orbis (Oncology)

- The first Innovation Passport approval, before the end of February,2021, was for Belzutifan, a treatment developed by MSD (UK) for adults with a rare condition, von Hippel Lindau disease (a genetic disorder that causes cancer). The award of this designation marks another first: the successful partnership between the MHRA, NICE and the SMC in making effective joint decisions and awarding Innovation Passports: https://www.gov.uk/government/news/first-innovation-passport-awarded-to-help-support-development-and-access-to-cutting-edge-medicines

- The majority of activity is currently in products in late development stage but with 5 early stage products. It is expected over time that this balance will shift to more early stage than late stage development products.

- The MHRA updated the ILAP webpage at the end of March – merging the previous 4 pages to one with links and some clarifications based on common questions we had received from industry.

2.6 **ILAP patient reference group**

The 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. There are several stages within ILAP, where patient involvement is being developed to ensure that patient views can be meaningful, enabling patients to influence the development and approval of products that will benefit them. Embedding the patient voice in ILAP processes will address some of the concerns raised in the ‘First do no harm report’ and support the agency’s strategic ambition to become a more patient focussed regulator.

2.7 An ILAP Patient Reference Group has been set up that will initially run as a pilot for six months and comprises sixteen patients /patient representatives. Members have been appointed by the MHRA, NICE, and SMC and reflect both the spread of interests and expertise required. The group will:

- Support the ILAP development to continuously improve how patients and patient representatives are involved, helping to ensure that the patient expertise and experience is impactfully represented in the process
- Participate in the ILAP Steering group (a cross partner group designed to deliver the ILAP), supporting the decision making for the Innovative Passport designation step
- Support the development of the ILAP Patient Engagement Tool

2.8 Partnership working with NICE and SMC:

The MHRA has worked more closely together with NICE and SMC colleagues and we have forged a stronger relationship during the co-development of the ILAP. Much has been achieved in terms of the design and implementation of the ILAP by working together. The high volume of applications to date is recognition of the uniqueness and the attractiveness of the ILAP ambition, delivering safe and early patient access to innovative medicines.

Now the ILAP is coming out of its first phase of development (successful launch, growing maturity in the operating model), we can consider what is the optimal framework that strengthens our relationship in a governance structure that delivers for all organisations. In order to do this, there is work ongoing to development a specific ILAP Partnership Agreement which would provide greater certainty in terms of delivering the elements of the pathway (Innovation Passport, Target Development Profile, Tools of the Toolkit), and offer a blueprint for resource allocation and planning: service level agreements and resourcing, financial impact of ILAP delivery, data and information sharing, approach to communications and strategic development of the ILAP. Closer working with colleagues from across the UK health system is attractive to industry and fulfils the ambition from the Accelerated Access Review (AAR) to create a ‘lit runway’ to patient access, streamlining development programmes to ensure faster patient access.

2.9 Resource planning and fees:

Fixed fees are currently in place for the Innovation Passport (fee: £3,624) and initial Target Development Profile (TDP fee: £4,451). There is ongoing work to consider the fees for the different tools of the toolkit. The current fees for the Innovation Passport and Target Development Profile were bench marked at launch to the closest fees for similar activities where available. Early work on delivering ILAP suggests that these fees will not capture the full cost of delivery. Clear benefits of the TDP concepts were noted during the pilots and delivering the TDP requires significant expert and operational resources. We are considering how to streamline the approach and ensure that the right expertise is available at the right time without over-committing. However, based on the very strong demand to date, consideration is needed in order to cover the costs of the critical mass of expertise to support ILAP work.

3. Proposal

3.1 The following items relate to the ILAP in the Delivery Plan:

Deliver better patient and public involvement to ensure we put patients first

- Making patient involvement more prominent following the implementation of the Medicines and Medical Devices Act and a new Innovative Licensing and Access Pathway that aims to ensure that patients are involved meaningfully at every stage of the process (objective 4)

Overhaul clinical trials system to support innovation and reduce time to approval

- Promote the Innovative Licensing and Access Pathway Novel Trial Design Tool in partnership with the wider health ecosystem by **Q2, 2022/23**

Develop and deliver the agency's future strategy and approach for access to medicines and devices

- Further develop the Innovative Licensing and Access Pathway concepts and tools, in collaboration with the National Institute for Health and Care Excellence and the Scottish Medicines Consortium to create a world-class first port of call for medicines development and access by **Q3, 2021/22**

3.2 What are the development opportunities that will have the biggest impact on patients?

The ILAP offers a unique opportunity to embed the patient voice right from the beginning and the Patient Reference Group will improve how patients and patient representatives are involved in our regulatory decision making. The ILAP ambition of speeding up the time to market, providing patients with access to medicines as soon as it is possible to demonstrate that the benefits outweigh the risks. Novel innovative approaches and continuous benefit risk assessment integrating real world data supports the paradigm shift in access.

3.3. Could ILAP become a mainstream route of medicine licensing?

The ILAP entry criteria are broad and inclusive. The creation of the TDP and toolkit are attractive offers to industry with partnership working. Early feedback has suggested that companies who may have not wished to engage in the UK are now taking a second look based on the ILAP offer – as an example an email quote below from a law firm who advise industry sent to OLS and shared with the agency:

'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. However, everyone is looking careful to see if the procedure delivers the wanted results'.

Based on early interest, ILAP could become the main route for medicine licensing in the UK and the UK could become the "go to place" to bring medicines to patients first.

3.4 How could ILAP fit with other routes (e.g. EAMS) and will it replace some/all others?

The Early Access to Medicines Scheme (EAMS) covers a short window of patient access towards the end of a development programme when the clinical data are reasonably mature and before marketing authorisation. The intention of EAMS is not to influence the content of a development programme but instead to facilitate patient access based on data generated by the company. In addition, the criteria for EAMS are significantly more stringent than ILAP, with the need in the criteria to demonstrate major advantage over existing products, a much higher bar than ILAP. The reason for this criterion is to ensure that the prescribing hierarchy is maintained – a prescriber only prescribes an unlicensed medicine or off label in areas of unmet need where it is demonstrated that the patient has an individual need and a licensed product is not sufficient.

EAMS remains an important flexibility that is still relevant even with the ILAP launch. It is likely that EAMS will be used as part of a portfolio for patient access activities in ILAP but it will not be suitable for all ILAP products (there is no major advantage for example). There may also be products that have not engaged with the ILAP but where EAMS remains an attractive offer for them to work in the UK regulatory system earlier than otherwise. A future EAMS Statutory Instrument (SI) to amend the Human Medicines Regulations will further enhance the attractiveness of using EAMS as a vehicle for earlier patient access and real-world data collection.

3.5 How could ILAP link seamlessly with clinical trials regulation and safety surveillance?

Clinical trials are an integral component to the ILAP's end-to-end approach and a number of tools of the toolkit support clinical trials. The TDP offers a specific framework for discussions including the location of clinical trials in the UK. In addition, the Health Research Authority (HRA) and the National Institute of Health Research (NIHR) are supporting ILAP partners who can for example provide advice as to whether innovative clinical trial proposals are deliverable.

In terms of surveillance and safety monitoring, the Continuous Benefit Risk Assessment integrating Real World Evidence (RWE) tool offers:

- optimal identification, access and timely delivery of decision-relevant data for regulatory and reimbursement bodies
- use of RWE and continuous assessment of emerging evidence to monitor safety and efficacy
- a proactive, feasible and sustainable approach to data collection covering both efficacy/effectiveness and safety aligned with key stakeholders
- a unique service which encourages and facilitates the use of RWE to support the benefit-risk profile

3.6 Could ILAP be expanded for use in medical devices?

ILAP answers a particular challenge for innovative medicines. The medical devices regulations and the MHRA's function leads to different challenges for medical devices. This challenge needs to be addressed in an innovative manner, but this will divert from the pathway set up in ILAP. The medical devices division have been working closely with our partners in NICE to establish an appropriate route for medical devices – the Critical Need Access Pathway. Following the UK exit from the EU, it is important for the MHRA and NICE to work more closely together to ensure UK patients have early access to effective and innovative devices in a safe manner. The MHRA can now look beyond the confines of the Medical Devices Directive to consider new regulatory opportunities.

The proposed Critical Need Access Pathway (CNAP, under review) route builds on MHRA's current exceptional use route that is available to manufacturers who wish to supply their devices in emergency situations. These can be approved on a named patient basis or as a broader derogation, as was seen in response to the demands of the pandemic. This new pathway takes this further in two key ways:

1. it creates a regulatory 'sandbox' for innovators that crucially will have healthcare system buy-in, and
2. it involves NICE as a core partner to ensure that support for health technology assessment (HTA) is built into the pathway from the start.

From a regulatory perspective, the Directives are often described as burdensome and overly complicated. SMEs more frequently feel the brunt of the requirements and the cost of generating the necessary data to achieve a CE mark. From an HTA perspective, the evidence required to demonstrate real-world effectiveness and economic impact are often lacking, even if a CE mark can be obtained. Whilst the Directives are vital in ensuring that medical devices on the UK market are safe and perform as intended, there is an argument that truly innovative devices that offer key therapeutic benefits for rarer and more challenging conditions are often thwarted at the research stage and therefore delays for patient access can occur.

MHRA and NICE along with other key partners can join forces to offer a supported research route where healthcare system buy-in is approved. This would allow manufacturers, big or small, to provide their device to healthcare professionals and patients at the earliest, yet safe, opportunity. This would enable them to generate real world clinical and economic data for their device, supporting these vital devices along the route to market.

The CNAP is primarily aimed at supporting innovative devices and the notion of innovation in medical devices differs from that in medicines. It can appear as 'big bang' completely novel types of devices or it can be smaller, more subtle iterations, but equally may open the door to new indications for use that will benefit a new patient group.

Innovative medical devices that could make a real difference to peoples' lives are not always able to reach the market early enough because of disproportionate or unsuitable evidence burdens that unduly prevents patients from accessing them. In other cases, the evidence package is complete, but the time taken to obtain authorisation delays access for patients where there is a critical need. This new pathway offers the opportunity for real value for patients in the UK to receive devices that can offer them potential benefits where other options have not been able to.

Ensuring healthcare system buy-in also addresses the 'attractiveness' of the UK as a place to conduct global leading research and device development. The Government's ambition is to ensure that the exit from the EU does not damage the UK's standing in the research arena.

3.7 How could ILAP be funded or preferably become financially sustainable?

There are opportunities for fee for service in the ILAP. As part of the embedding process, consideration is being given to the fee structure and cost recovery ambition. Sustainability will need to come from a combination of fee for service, increases to current fees and government support as part of supporting the life science ecosystem.

3.8 What other partners could be brought into ILAP to support Life Science Sector Vision?

There are current discussions with NHSE, NIHR, HRA, Wales and Northern Ireland around greater interaction in the ILAP. The MHRA has been working collaboratively with the Accelerated Access Collaboration (AAC) since inception and contributed significantly to the Accelerated Access Report. The MHRA was asked by the AAC to 'explore ways to facilitate enhanced collaboration between stakeholders, considering alignment of data requirements where possible and provide bespoke and timely advice to developers across the whole of the medicines regulatory pathway in support'. The ILAP fulfils this ambition but includes a much wider range of product types.

3.9 A proposed roadmap of how and when ILAP will be developed with key deliverables, timescales, resource requirements and outcome measures

The current delivery pipeline within MHRA provides project management and supporting services for the ILAP project until October 2021. The development and implementation of the initial technical solution to support ILAP will be complete in mid-October 2021. As the ILAP process evolves and as processes are refined, new requirements will be captured that are expected to lead to further technical enhancements. Additional partners that are brought on board are also likely to add to requirements and the challenges for integration of systems across regulatory bodies will need to be mapped and delivered. There will be a need to work closely with the operational teams in Licensing and Devices, as well as partner organisations, to capture requirements and evolve the delivery plan for ILAP over the next 3 – 4 months.

The impact of ILAP and other initiatives underway within and outside the Agency (e.g. combined review of Clinical Trials with HRA under Combined Ways of Working) are being considered with the Department of Health and Social Care (DHSC) in order to understand the future regulatory landscape for the UK in which ILAP sits. The close alignment of clinical trials and ILAP already demonstrates the need to produce a roadmap to see where initiatives across the system begin to dovetail with each other so that we can understand the potential integration and interoperability requirements.

4. Recommendation

4.1 The Board is asked to endorse the proposals and recommend any other areas for development. The most pressing strategic issues are embedding patient voice in the ILAP, creating a sustainable model for delivery from a resourcing perspective and finalising the partnership agreements with ILAP partners, which needs to include consideration of the strategic fit across the broader health landscape.

Samantha Atkinson
9 June 2021

Medicines & Healthcare products Regulatory Agency

BOARD MEETING HELD IN PUBLIC

15 June 2021

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

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

1. Executive Summary

1.1 At the third meeting PSEC agreed the wording on a change to its Terms of Reference. It discussed a report on the Cumberlege deliverables and asked for more data, detailed examples, and explanations. Finally, it discussed its work programme.

2. Introduction

2.1 The third full meeting of PSEC was held on the 4th June 2021. A meeting was also held with Non-Executive and lay representatives on the 28th April to seek input into the Communications Strategy which was presented to the Board meeting in May.

3. PSEC then discussed each of the following items:

3.1 Documented business of PSEC available for public view

At the April 2021 meeting of the Board, approval was given for a change in the Terms of Reference regarding the minutes of PSEC being in the public domain. It was agreed that the PSEC Board Assurance Report, due to its timeliness and summary of discussions, would be the document available to the public. There was some discussion on whether this was the right course of action and PSEC agreed that this could be reviewed at the end of the calendar year. The intention is to ensure that the public were able to view a clear account of how PSEC conducted its business in a timely way. PSEC then agreed to replace the section headed "Minutes" in the Terms of Reference with the section heading of "Transparency" and to include agreed wording on PSEC Board Assurance Reports being the publicly available account of the committee's business.

3.2 Review of the Cumberlege Deliverables

Recommendation 6 of Cumberlege (the Independent Medicines and Medical Devices Safety Review (IMMDS)) called for substantial changes by the Agency, particularly in relation to adverse event reporting and medical device regulation. In concert with this, the Agency has been working on deliverables for some time, which are already incorporated into the Agency's Delivery Plan 2021/2023. The work on IMMDS Recommendation 6 is one of the main reasons that the Patient Safety and Engagement Committee exists.

PSEC was informed of the work of the DHSC and its Patient Reference Group. The DHSC is expected to respond soon to the recommendations in the IMMDS Review. PSEC then considered the report on the Agency's progress in responding to the recommendations of the IMMDS. Although it is clear from the work discussed at Board meetings, new strategies out for consultation, and the opportunities available through the new Act, that progress has been made, the Committee considered that the level of detail and evidence required by it were not evident in the report.

It became clear in the response of Executives that some data on impact of activities, which PSEC strongly favours, is available. There might be other areas, for instance changes in culture, which are more difficult than changes in activities to measure. PSEC encouraged Executives and their teams to use the Committee to discuss what evidence is needed and how impact and outcomes can be measured. The need to focus on those patients who experience harm was emphasised. This will be an area of focus for the newly appointed Chief Safety Officer.

Members commented that although listening to patients by the Agency was to be encouraged, patients would also want to see responses to their comments. Some patients would also like to be more actively involved.

PSEC would also like to receive a list and examples of publications for patients that the Agency was producing. It should be accompanied by a commentary on how patients and the public were involved in developing these publications, where they can be found and how they are distributed.

The discussion ended with greater clarity on what members of PSEC were seeking in terms of evidence of impact. Specific comments on the paper would be sent to the authors.

3.3 **Work Programme**

PSEC discussed its draft Work Programme for the rest of the calendar year. The Committee had some general suggestions on the Programme as well as some specific items to add. The Work Programme needs to:

- Not just look at process but impact and outcomes.
- Cover the full range of the Agency's work.
- Prioritise areas of high risk.
- Discuss measures used in the balanced scorecard.
- Look at cross cutting issues such as culture.
- Co-ordinate with Board agendas so that PSEC can review relevant topics in advance of the Board: for example, an update on Yellow Card should return to the Committee in October before Safety Connect is reviewed by the Board in November.
- Include steering discussions as well as assurance items.
- Be flexible enough to accommodate any issues that arise that need addressing more urgently.
- Include extra and special meetings of PSEC, including joint meetings with ARAC.

Some specific suggestions included looking at the developments in medical device regulation; diversity and inclusion; and to ensure returning items such as CPRD governance are given a return date to the Committee, even if they are in the next calendar year.

The Chair of the Committee and the new Governance Office will make amendments to the content and format of the Work Programme and will circulate it prior to the next full meeting of PSEC in August.

4. Joint meeting with ARAC

The Patient Safety and Engagement Committee will be holding a joint meeting with the Audit and Risk Assurance Committee in July to discuss co-ordination of work.

5. Conclusion

PSEC is shaping its work programme and intends to schedule items that support the Board. It will work with ARAC to ensure that items of higher risk are scrutinised appropriately.

Mercy Jeyasingham
8 June 2021