



Medicines & Healthcare products Regulatory Agency

Minutes (final)

Title of meeting	Corporate Executive Team formal monthly meeting
Date	04 August 2020
Time	08.30 – 13.30
Venue	Videoconference
Chair	June Raine
Attendees	CET
Apologies	Christian Schneider

CET Attendees

June Raine	Chief Executive Officer (Chair)
Jon Fundrey	Chief Operating Officer
Boryana Stambolova	Deputy Director of Finance
Marie Donatantonio	Deputising for Director of the National Institute for Biological Standards & Control
Rachel Bosworth	Director of Communications
John Quinn	Director of Transformation
Vanessa Birchall-Scott	Director of Human Resources
Sarah Branch	Interim Director of Vigilance and Risk Management of Medicines
Graeme Tunbridge	Interim Director of Devices
Samantha Atkinson	Director of Inspection, Enforcement and Standards
Siu Ping Lam	Director of Licensing
Carly McGurry	Change Strategy Lead
Janet Valentine	Director of the Clinical Practice Research Datalink
Jonathan Mogford	Director of Policy
Elizabeth O'Neill	Deputy Director, MHRA, Medicines & Pharmacy, Government Legal Department

Additional Attendees

Keith McDonald, Liz Baker and Julian Bonnerjea (Lic) for item 7: EU Exit transition
Rachel Arrundale (Pol) for item 8: Future of Regulation
[REDACTED] for item 9: COVID-19 Lessons Learnt
Julian Bonnerjea (Lic) for item 10: Development of the Innovation Office
[REDACTED] for item 11: Agency Branding
Mick Foy (VRMM) for item 12: Yellow Card Biobank
Janine Jolly (Devices) for item 13: NaPSAC Alerts
[REDACTED] for item 14: Portfolio update
[REDACTED] for item 15: BAME Equality
[REDACTED] for item 16: 2020/21 SCS Pay Award
[REDACTED] item 17: Accessibility across our digital channels
[REDACTED] for all items.

1. Apologies and Announcements

1.1 Apologies were received from Christian Schneider.

2. Draft minutes of the 07 July CET meeting (CET/20/204) including table of actions and final minutes of the 02 June CET meeting (CET/20/205)

2.1 The draft minutes of the 07 July meeting were reviewed, with the CET adding some minor comments. The CET reviewed and provided updates on the table of actions. The final minutes of the 02 June CET meeting were noted.

3. Final minutes of June 2020 Board meeting (CET/20/206)

3.1 The CET noted the final minutes of the June 2020 Board meeting.

STRATEGY

4. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

5.1 [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

6. Finance Report (CET/20/210)

6.1 Boryana Stambolova presented the Agency's Year To Date (YTD) June 2020 (Q1) financial performance compared to YTD budget and the same period last year. The CET noted that the Agency has a YTD operating surplus of £0.5m, compared to a budgeted deficit of £1.5m. Compared to the same time period last year, the YTD operational surplus is £0.9m less as a result of the decline in revenue (mainly due to lower regulatory income (inspections and licensing) combined with the now complete absence of EMA revenue) and increase in Business As Usual (BAU) costs.

6.2 The CET noted that pay costs remain approximately 2% below budget; it is expected that pay costs growth will accelerate post the 2020/21 pay settlement later in the year. Non-pay costs are also below budget across most spend categories, with major underspend in staff-related non-pay costs, training, accommodation, medicines testing and lab costs, and external services. With regards to Change Costs, the YTD change costs are £1.7m compared with a full-year budget of £21.4m. It was noted that some of the bigger change projects (such as the NI Protocol, CIVS, and NISBC Capital programme) and technology infrastructure spend are expected to come later in the year; despite this YTD expenditure has been minimal and Performance Committee has expressed concern over the achievability of the forecast. The CET noted that the in-year forecast will be reviewed at the Investment Board and will be challenged with regards to achievability.

6.3 [REDACTED]

[REDACTED] The CET noted that work which had slowed down due to the COVID-19 pandemic is beginning to pick up again.

6.4 The CET noted that the full year forecast is an increased operational deficit of £14m, £5.1m worse than the budgeted deficit of £8.9m. The key drivers for this deficit are a reduction in regulatory income; partly offsetting these forecast shortfalls is a forecast £1m increase in standards sales at NIBSC. Operating costs are forecast to be £0.8m less than budget with a large forecast overspend in pay costs (£2.9m) being more than offset by a reduction in non-pay costs. The CET noted that over the next couple of months there is a high amount of turnover ongoing in Finance; recruitment is ongoing however there will inevitably be some loss of corporate knowledge so this must be accounted for.

6.5 [REDACTED]

7. [REDACTED]

[REDACTED]

[REDACTED]

7.4 [REDACTED]

[Redacted]

[Redacted]

8. Future of Innovative Regulation (CET/20/208)

8.1 Rachel Arrundale presented an update on the Future of Innovative Regulation: the MHRA/OLS project. The CET noted that work has been proceeding at pace; a series of discussions with key stakeholders has been held, and a series of 6 workshops is being held 3-7 August. There are two overarching workshops – on medicines and medical devices and four deep dive workshops on clinical trials, vaccines, ATMPs, and cell/gene therapies. The CET noted that in relation to patient involvement, it is important to ensure that input is sought from a wide range of stakeholders as well as the most relevant stakeholders in each area. The CET noted that a final report will be presented to Lord Bethell by 14 August; the CET reviewed the draft report structure with anticipated findings.

8.2 [Redacted]

8.3 [Redacted]

[Redacted]

9. [Redacted]

[Redacted]

[Redacted]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

10. Development of the Innovation Office (CET/20/213)

10.1 Julian Bonnerjea presented an update on options to further develop the Innovation Office (IO). The CET noted that following the Social Media campaign highlighting the IO, the Regulatory Group suggested that the IO adopt a proactive approach and follow up previous enquiries. The Group also requested information on the conversion of IO queries into fee-earning activities such as scientific advice meetings and clinical trial applications. The IO has grown steadily over the past 7 years and is now beginning to outgrow the limited resource of 0.5 FTE allocate to it. Some additional resource will be required to provide an efficient service and to introduce the proactive follow-up procedure. The CET suggested that an internal fixed term secondment could be a way to manage this.

10.2 [REDACTED]

10.3 [REDACTED]

[REDACTED] The CET noted that a large proportion of enquiries come from academics and SMEs, which is encouraging as this is the target audience and outreach activities have been ongoing to engage with these groups.

10.4 The CET commented that feedback from industry over the COVID-19 period indicate that industry really value speed and a personal service from the Agency; this is an important factor to consider for the Agency's future business model; it was noted this is resource intensive. The Agency offers the opportunity to utilise expertise and data sources such as CPRD. [REDACTED]

Action: Consider internal fixed term secondment to the IO. Develop strategy paper with proposals [REDACTED] Present this at the September 2020 CET meeting.

11. [REDACTED]

[REDACTED]

[REDACTED] e.

11.3 [REDACTED]

[REDACTED]

[REDACTED]

12. Yellow Card Biobank (CET/10/215)

12.1 Mick Foy presented an update on the Yellow Card Biobank. The CET noted that progress has been made in relation to funding, governance steps and stakeholder

engagement to take this project forwards. The CET noted that funding from OLS has been agreed and advertisements for three new posts are now live. A project board for the YC Biobank has been established under the SafetyConnect programme with representatives from across the Agency; the first meeting of the project board will be on 12th August 2020.

12.2 [REDACTED]

Action: Proceed with recruitment for these posts; continue discussions with pharmacogenomic experts identified.

13. National Patient Safety Alert Committee (NaPSAC) Alerts (CET/20/216)

13.1 Janine Jolly presented an update on plans to communicate critical patient safety messages to the health service using National Patient Safety Alerts following a successful NaPSAC credentialing process in February 2020. The CET noted that from September 2020 the Agency will be issuing safety communications, likely to cause death or disability in any one year, via a new National Patient Safety Alert template. These messages will be distributed via the Central Alerting System (CAS). [REDACTED]

[REDACTED] IE&S will work with Janine Jolly to take this forward.

Action: Issue safety communications via the new template from September 2020. [REDACTED]

GOVERNANCE AND DELIVERY

14. Portfolio Update (CET/20/218)

14.1 John Quinn and [REDACTED] presented an update on the Agency's Enterprise Portfolio. The CET noted the updates on EU exit, the Change Strategy, Agency infrastructure, and divisional projects. The CET acknowledged there are interdependencies between many projects within the Agency and gaps and overlaps must be identified. The uncertainty and complexity around EU Exit transition was noted as a key risk. The CET noted that with increasing amount of change expected later in the year there will be certain financial and resource implications. It was noted that CET may be required to make calls on priority in the next couple of months.

14.2 The CET noted that an SMT review will take place regarding NISBC capital investment. It was noted that the COVID-19 pandemic meant there was a slow start to the year; however there is a push now to bring forward bigger maintenance and building projects at NIBSC. The CET noted the interdependencies in projects within the Agency and agreed that it is important that these are managed centrally so they are reduced.

Action: Present an update to CET in September 2020 on reprofiling of projects.

15. Black, Asian and Minority Ethnic (BAME) Equality – Information Analysis and Related Recommendations (CET/20/217)

15.1 [REDACTED] presented a report exploring current information in relation to BAME equality across the Agency. The CET noted that following the PHE disparities report on COVID-19

deaths and nationwide protests sparked by events in the United States, the issue of BAME inequalities has had heightened attention in the UK and the Civil Service, along with other public bodies, have been further exploring race equality, reflecting on boundaries to progression for BAME staff and wider direct and indirect discrimination that may reduce opportunities and success.

15.2 Within the Agency this heightened focus has led to the creation of a new BAME staff network, alongside the CET request for a deep dive analysis of current information. The CET reviewed the recommendations of this report and endorsed these. The CET noted the proposal for a Non-Executive Director (NED) of the Board to act as a Diversity and Inclusion champion; it was agreed that the NED must have a defined role. A pan-agency Diversity and Inclusion Framework will be set up, focussing on each protected characteristic group with actions monitored and assessed quarterly through the Diversity and Inclusion Group and contributed to by the various Inclusion Groups. The Agency Public Sector Equality Duty report will be further extended to include data sets relating to pay and grade.

15.3 The CET noted that there will be work undertaken on training and development, and training in unconscious bias beyond the online CSL package. Reporting of discrimination concerns will be built upon; social mobility data will be reviewed and built upon in 2021. The CET noted this is an enormously important area of work and it is vital that staff have confidence in the Agency's ability to tackle discrimination. The CET requested more information on recruitment and employment opportunities for BAME staff.

Action: Take forwards these recommendations; ensure the NED Diversity and Inclusion champion has a defined role; present the CET with an update with more information on recruitment and employment opportunities for BAME staff; provide an update to staff at the All Staff Meeting.

16. 2020/21 SCS Pay Award (CET/20/219)

16.1 ██████████ presented an update on the SCS pay guidance. The CET agreed that in line with Delegated staff, both SCS payments should be made as soon as possible and separately if necessary. The CET agreed that all pay anomalies should be reviewed at CET meeting on 25 August based on criteria already circulated and in line with Senior Salaries Review Body (SSRB)'s recommendations. CET reviewed the options for individual awards. In previous years the award has been split between SCS1 and SCS2 as in previous years; it was noted there is a second option for SCS1 and SCS2 to be paid the same amount. The CET supported the proposal that the same bonus be paid for SCS1 and for SCS2, to bring the Agency in line with other organisations.

17. Accessibility Across our Digital Channels (CET/20/231)

17.1 ██████████ presented a paper reporting the current status of the project to meet accessibility standards across the agency's digital real estate ahead of the September 2020 deadline for complying with the regulations. The CET noted that due to various challenges, not all sites will be ready by the deadline. Legal advice has been sought on the risks of deprioritised content not being made accessible by the deadline. Accessibility statements will be prepared for these sites for the deadline; the Agency will be able to make claims on what amounts to a disproportionate burden in relation to a planned roadmap of website development and lack of resource availability. The CET noted that existing priority content on gov.uk will be compliant by calendar year end. The CET noted the update and endorsed the approach for delayed but full compliance.

INFORMATION

18. NIBSC monthly update for CET (CET/20/221)

18.1 The CET noted the NIBSC monthly update.

19. Final minutes of June 2020 Regulatory Group meeting (CET/20/222)

19.1 The CET noted the final minutes of the June 2020 Regulatory Group meeting.

20. Updates from Cross-Agency teams

EPMO Governance Board	CET/20/223
Performance Committee Meeting	CET/20/224
Policy and Procedures Committee	CET/20/225
Audit and Risk Assurance Committee	CET/20/227

21. Agreement of 01 September 2020 CET agenda (CET/20/230)

21.1 The CET reviewed and provided comments on the 01 September 2020 draft CET agenda.

22. AOB

22.1 The CET considered an AOB item on return to work sites following the COVID-19 pandemic. It was noted that staff have been split in to 4 groups depending on personal preference identified through surveys and 121s with managers, with group 1 to be returning to work sites first. The CET noted there are capacity issues relating to groups 2 and 3 returning to sites, due to increased social distancing required. The CET endorsed allowing staff back to work sites in small numbers, noting the risk of a second wave. It was noted that the accommodation strategy will be taking forward proposals related to new ways of working. Staff will be communicated on this matter at the All Staff Meeting. Health and safety must be priority and risk assessments undertaken if necessary. Further discussions will be held at a future CET meeting.