

Medicines & Healthcare products Regulatory Agency

Minutes (Final)

CET/20/233

Title of meeting Corporate Executive Team

formal monthly meeting

 Date
 07 July 2020

 Time
 09.00 - 13.00

 Venue
 Videoconference

 Chair
 June Raine

Attendees CET

Apologies Jon Fundrey, Samantha

Atkinson

CET Attendees

June Raine Interim Chief Executive Officer (Chair)

Christian Schneider Director, National Institute for Biological Standards & Control

Vanessa Birchall-Scott Director of Human Resources Rachel Bosworth Director of Communications

Andrew Gray Deputising for Director of Inspection, Enforcement and

Standards

Janet Valentine Director of the Clinical Practice Research Datalink

John Quinn Director of Transformation

Boryana Stambolova Deputising for the Chief Operating Officer

Siu Ping Lam Director of Licensing
Graeme Tunbridge Interim Director of Devices

Sarah Branch Interim Director of Vigilance and Risk Management of Medicines

Jonathan Mogford Director of Policy

Elizabeth O'Neill Deputy Director, MHRA, Medicines & Pharmacy, Government

Legal Department

Additional Attendees

Kirsty Wydenbach (Lic) and Rachel Arrundale (Pol) for item 6: COVID-19 vaccine

Mick Foy (VRMM) for item 7: Pandemic vaccine campaign ADR analysis (TD) for item 8: Transition Taskforce – update and discussion

Penny Carter (NIBSC) for item 10: Accommodation strategy

for item 11: Patient Engagement Strategy – update

for item 12: Customer Service Centre update

Rachel Arrundale and for item 13: Future regulations

for all items.

1. Apologies and Announcements

1.1 Apologies were received from Jon Fundrey and Samantha Atkinson.

- 2. Draft minutes of the 02 June CET meeting (CET/20/181) including table of actions and final minutes of the 05 May CET meeting (CET/20/182)
- 2.1 The draft minutes of the 02 June 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 05 May CET meeting were noted.
- 3. Final minutes of May 2020 Board meeting (CET/20/183)
- 3.1 The CET noted the final minutes of the May 2020 Board meeting.

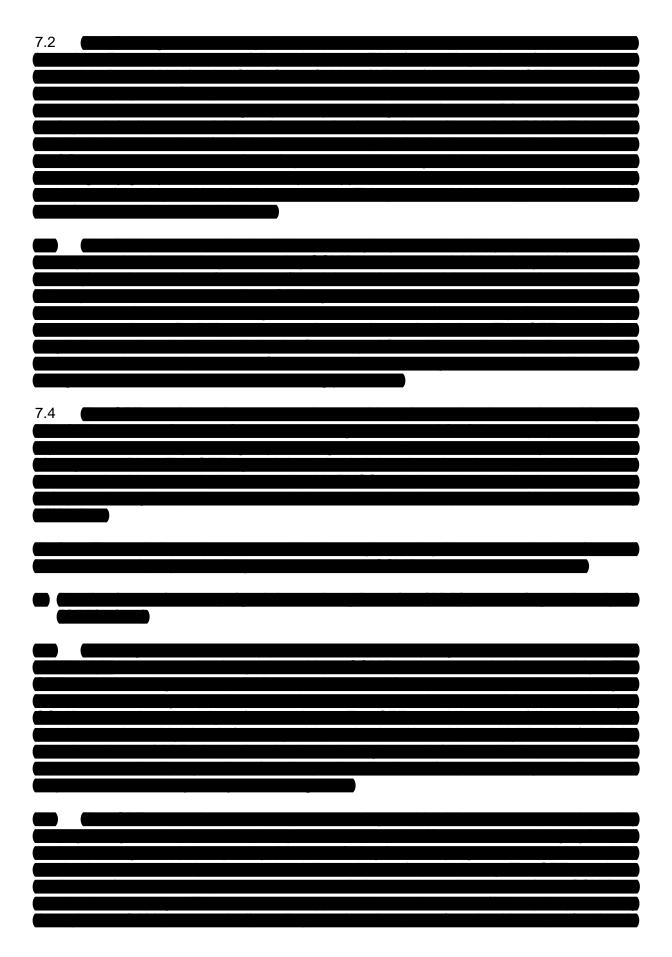
STRATEGY

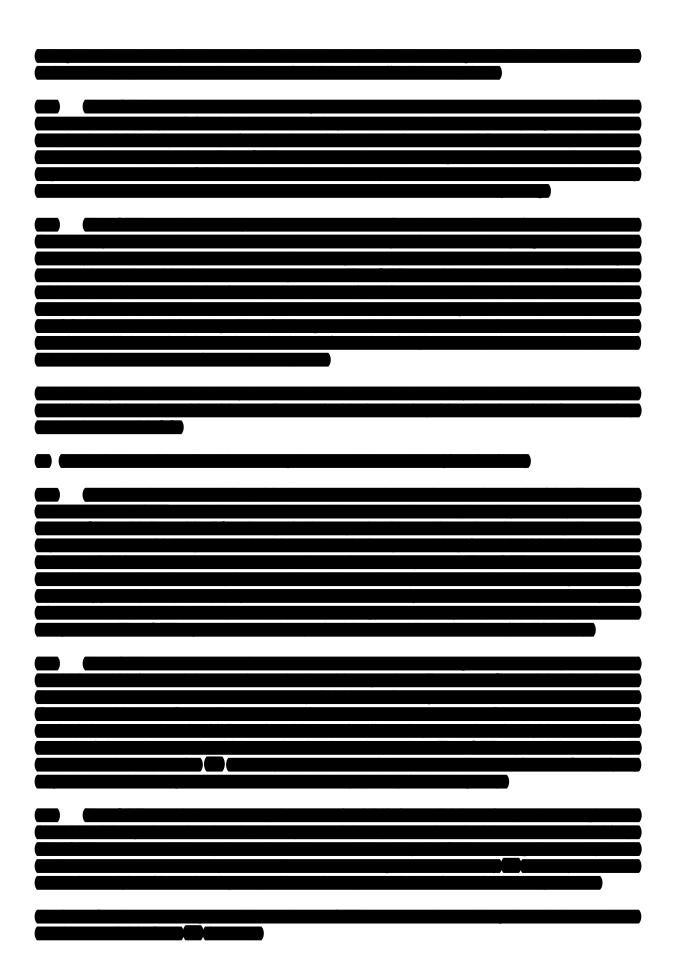
4. Cumberlege Review - verbal update

4.1 June Raine gave a short update on the preparations for handling the report of the Independent Medicines and Medical Devices Safety Review (IMMDSR), chaired by Baroness Cumberlege. The CET noted that the report of the IMMDSR is being published on Wednesday 8th July. Extensive media coverage is anticipated. A draft MHRA statement of response has been prepared and is with the DHSC press team for approval. Staff will be kept informed of developments through INsite updates and a video blog, and at Senior Leadership Group and All Staff Meetings. The recommendations of the Review will be carefully considered.

5. Change Strategy - verbal update (CET/20/184)

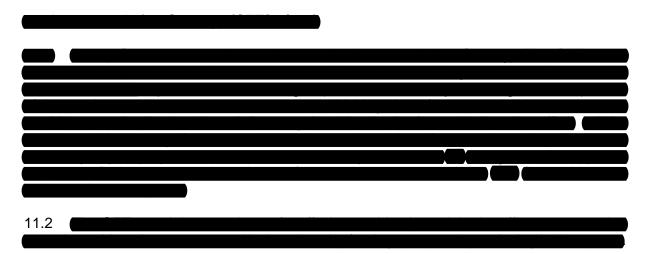
5.1 June Raine gave a short update on the progress with the Change Strategy. The CET noted that an update was given to staff at the All Staff Meeting (ASM) and to Board members at the last Board meeting. There have been a number of questions from the Board which are being responded to. The CET commented that there was a large audience in the ASM and noted there were a number of wide-ranging questions on the change strategy. Work continues in this area.

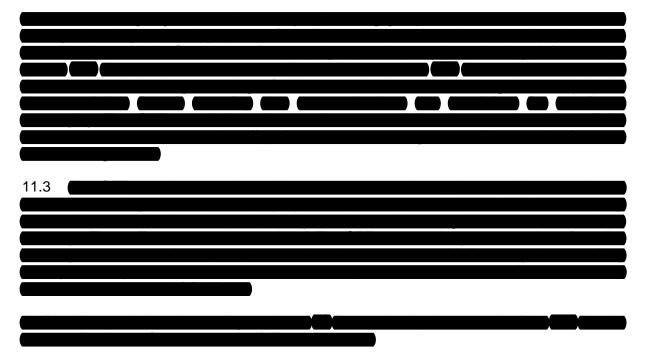




10. Finance Report (CET/20/189)

- 10.1 Boryana Stambolova presented the Agency's Year To Date (YTD) May 2020 financial performance, compared with the YTD budget and the same period last year. The CET noted that the operational deficit increased slightly in May bringing the YTD deficit to £0.5m. Trading income is £1.5m below the YTD budget, and is less than last year. With DHSC income slightly higher, the YTD total income shortfall vs. budget and last year is £0.9m and £0.8m respectively. The income shortfall in comparison with the budget is more than offset by lower operating costs along with below budget change costs, which have resulted in a YTD operating deficit of £0.5m compared to a budgeted deficit of £1.0m.
- 10.2 Compared to the same period last year, the YTD operational deficit is nearly level due to lower non-pay costs compensating for the decrease in revenue. The latter is mainly due to lower regulatory income (inspections and licensing) combined with the now complete absence of EMA revenue. The YTD income was approximately 10% less than budget in the Regulator and CPRD while NIBSC revenue was 10% higher. There has been a decrease in inspections therefore a decrease in inspection-related income. NISBC standard sales are generating a surplus; and CPRD income through clinical trials has not yet arrived but is expected throughout the year.
- 10.3 Overall YTD operating costs were less than budget. Pay costs are 1.5% below budget overall, however staff in post at the end of May were broadly in line with the funded posts. The CET noted that any additional vaccine deployment costs have been kept separate to ensure distinction between this and business as usual; this will aid calculating costs attributable to the pandemic.
- 10.4 Non pay costs are also below budget across most spend categories with the exception of ICT and external services in corporate however these are offset by lower costs in other areas. YTD change costs are £1.5m compared to the full year budget of £21.7m however some of the bigger change projects are expected to come later in the year. The CET noted that the 2020/21 corporate cost allocations model continues as agreed by CET in April 2019. The cash in the bank as of the 31st May 2020 was £92m. The CET noted £60m of this is reserves; a clear picture of how this money will be earmarked must be obtained.
- 10.5 The CET noted the update and requested trending graphs for future reports. The CET requested further clarity on contingent workers to help elucidate the impact the pandemic is having; this will be reviewed in the financial performance committee. It was noted that this information will feed into the future 'balanced scorecard'. The CET thanked Ms Stambolova and the finance team for the quality of financial advice to aid strategy development.





12. Patient Engagement and Involvement Strategy – update (CET/10/191)

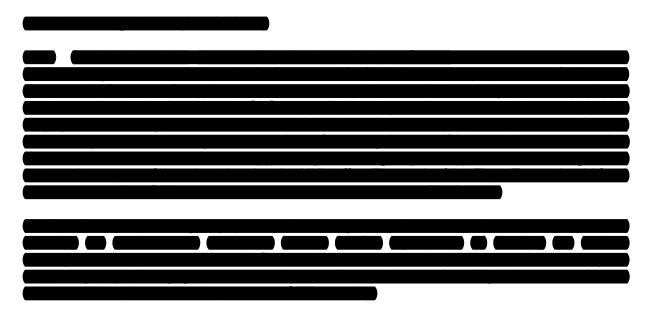
- 12.1 presented an update on the Patient Engagement and Involvement (PEI) Strategy 2020-25. The CET reviewed the draft PEI Strategy which is being developed with input from the newly formed external reference group. The CET noted that this work may change depending on the recommendations from the Cumberlege Review. This PEI Strategy work must link in with the IMMDSR Implementation Group once this is established. The CET recommended reviewing how other regulators such as the EMA engage with patients, to take this into consideration. It is important that engagement, transparency and clear communication are prioritised. Early involvement of patients and patient groups in innovative licensing procedures is a new area to explore; additionally when designing clinical trials, it is important to consider endpoints which are relevant to different patient populations.
- 12.2 The CET noted that patient perceptions of products may be different depending on the patient population for example patients suffering from a condition may have a different viewpoint compared with patients who have experience adverse incidents with a product. This will need careful consideration. The CET agreed it is key to have patient involvement early and systematically in innovative licensing. The CET also agreed that it might be helpful to hold a dedicated Mini Away Day session on this topic.

13. Customer Service Centre update (CET/20/192)

13.1 presented an update on the work of the Customer Service Centre (CSC). The CSC went live on the 23rd March and was launched with all staff working remotely due to the COVID-19 pandemic. The CSC rapidly ramped up its services and hours of operation to support the Agency's crucial role in the pandemic. The CET noted that consistent improvements are being seen month by month from the CSC. It was noted that wider divisional collaboration and support from colleagues is key to the success of the CSC. The CET thanked the team for the hard work in setting up the CSC and noted the progress. Information on response times is key but also satisfaction from the responses is also an important outcome to measure. A single tool for enquiry management and relationship management will be key for the future.

13.2 The CET noted that the current system is a minimum viable product at present; further developments will be possible in the future. The CET commented that the details of the next phase and resource requirements from several Divisions which have been unable to release staff resources need further clarification and reconsideration before this is progressed. The CET noted that a more integrated service and approach will be key to providing a better service to stakeholders.

Action: Report on enquirer satisfaction as well as response times. Draw together data of query response times across the Agency. Work to further develop a single tool for enquiry management across the Agency in future. Clarify details of phase 2 of the CSC project with Divisions unable to release staff resources and present this to CET.



15. Portfolio Update (CET/20/194)

15.1 John Quinn presented an update on the Enterprise Portfolio. The CET noted updates on EU exit, the Change Strategy, Agency infrastructure, and divisional projects. With regards to the Sentinel replacement, current work focussed on dependency management; this is a complex piece of work but is being taken forward at pace. It was noted that cuts have been made on helpdesk management which have been saving £0.25m a year. The CET noted there are risks related to capacity; delivery of change while all staff are working at home is a challenge. The CET agreed that the next few months' work will be critical; the portfolio will be revisited when the CET feel reprioritisation is required.

Action: Revisit the portfolio when CET feel reprioritisation is required. Continue progress on delivery.

INFORMATION

- 16. NIBSC monthly update for CET (CET/20/195)
- 16.1 The CET noted the NIBSC monthly update.
- 17. Final minutes of May 2020 Regulatory Group meeting (CET/20/196)
- 17.1 The CET noted the final minutes of the May 2020 Regulatory Group meeting.

18. Updates from Cross-Agency teams

EPMO Governance Board	CET/20/197
Performance Committee Meeting	CET/20/198
Policy and Procedures Committee	CET/20/199
Health and Safety Strategy Group	CET/20/200
Risk and Audit Liaison Group	CET/20/201
Diversity and Inclusion Group	CET/20/202

19. Agreement of 04 August 2020 CET agenda (CET/20/203)

19.1 The CET reviewed and provided comments on the 04 August 2020 draft CET agenda.

20. AOB

20.1 No items of AOB were raised.