



Medicines & Healthcare products  
Regulatory Agency

# Minutes (Final)

CET/20/233

<b>Title of meeting</b>	Corporate Executive Team formal monthly meeting
<b>Date</b>	07 July 2020
<b>Time</b>	09.00 – 13.00
<b>Venue</b>	Videoconference
<b>Chair</b>	June Raine
<b>Attendees</b>	CET
<b>Apologies</b>	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.



7.2 [REDACTED]

[REDACTED]

7.4 [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

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## 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 31<sup>st</sup> 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.

[REDACTED]

[REDACTED]

11.2 [REDACTED]

[REDACTED]

11.3 [REDACTED]

[REDACTED]

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

12.1 [REDACTED] 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 [REDACTED] presented an update on the work of the Customer Service Centre (CSC). The CSC went live on the 23<sup>rd</sup> 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.

[REDACTED]

[REDACTED]

[REDACTED]

## 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.