Medicines & Healthcare products Regulatory Agency

Minutes (final)

CET/17/207

Title of meeting	Corporate Executive Team formal monthly meeting
Date	06 June 2017
Time	09.00 – 12.00
Venue	G1, BPR
Chair	Ian Hudson
Attendees	CET
Apologies	Christian Schneider

CET Attendees

Ian Hudson	Chief Executive (Chair)
Rachel Bosworth	Director of Communications
Ian Feavers	deputising for Director of the National Institute for Biological Standards & Control
Jon Fundrey	Chief Operating Officer
John Quinn	Director of Information Management
John Wilkinson	Director of Devices
Gerald Heddell	Director of Inspection, Enforcement and Standards
Jonathan Mogford	Director of Policy
Janet Valentine	Director of the Clinical Practice Research Datalink
Vanessa Birchall-Scott	Director of Human Resources
Paul Wright	DH Legal Services
June Raine	Director of Vigilance and Risk Management of Medicines
Siu Ping Lam	Director of Licensing

Additional attendees

Andy Gregory and [Name redacted under section 40 of the FOIA (personal data)] for items 4: Brexit – update and discussion and 5: Implementation of the Devices Regulations

[Name redacted under section 40 of the FOIA (personal data)] for item 6: Phase 1 - BP Target Operating Model

[Name redacted under section 40 of the FOIA (personal data)] for item 7: Operational Excellence

[Names redacted under section 40 of the FOIA (personal data)], staff observers

[Name redacted under section 40 of the FOIA (personal data)] for item 14: Corporate Risk Register

[Name redacted under section 40 of the FOIA (personal data)] for all items

1. Apologies and Announcements

1.1 Apologies were received from Christian Schneider.

2. Draft minutes of the 09 May Corporate Executive Team meeting (CET/17/150) including table of actions and final minutes of the 11 April Corporate Executive Team meeting (CET/17/151)

2.1 The draft minutes of the 09 May meeting were agreed. The CET reviewed and provided updates on the table of actions. The final minutes of the 11 April meeting were noted.

3. Final minutes of the 24 April Board meeting and draft minutes of the 22 May Board meeting (CET/17/152)

3.1 The final minutes of the Board meeting of 24 April and the draft minutes of the 22 May 2017 Board meeting were noted.

STRATEGY

4. Brexit – update and discussion (CET/17/153)

4.1 [Redacted under section 35 of the FOIA (Formulation of government policy)]

5. Implementation of the Devices Regulations (CET/17/154)

5.1 John Wilkinson and [name redacted under section 40 of the FOIA (personal data)] presented an update on the implementation of the devices regulations. The Medical Device Regulations (MDR) and In Vitro Diagnostics Regulations (IVDR) will fully apply in EU Member States from 26 May 2020 and 2022 respectively. Devices have created a detailed operational programme plan to ensure that the MHRA meet our legislative requirements. This plan has been shared with colleagues across the Agency and key points of contact are being confirmed within other parts of the Agency to ensure that we have cross-Agency alignment in delivering against our legislative obligations.

5.2 An implementation steering group has been established which will map UK elements of the legislation; and take this work forward. There will be a number of new areas the Agency will be required to take on, which will require more resource. The Agency have a number of specific obligations to perform, such as increased market surveillance and economic audit of operators and manufacturers; or supervision of investigations of GCP audits of clinical investigation sites. The implementation steering group will be working to create pragmatic guidance for interpretation of the regulations. The CET noted that there is a more significant overhaul of the IVD regulations; therefore this has a 5-year implementation period. Currently 10-20% of IVDs go through notified bodies, however after this over 80% will; this is reflective in the resources needed in Devices on IVDs.

5.3 The CET noted that the issue with resource puts further pressure on the devices fees discussions; and this will need to be raised with DH. CAMD are undertaking a piece of work related to resourcing the regulations. The effects elsewhere on the Agency will need to be carefully monitored. There may be potential for issues in relation to funding from DH as this will be implementation of new EU legislation while Brexit is taking place. It was noted that there will be a requirement for fuller assessments for elements of companion diagnostics in future. The regulations mean a considerable amount of work; CET gave short term support for continued plans on the implementation. Over the longer term, ways to sustain funding will need to be resourced. Efficiency issues should also be addressed. Discussions should be held with DH with regards to funding for this work.

Action: Devices to work with finance to fund the resource required over the short term for implementation of the MDR and IVDR; hold discussions with DH with regards to longer term funding.

6. Phase 1 – BP Target Operating Model (CET/17/156)

6.1 [Name redacted under section 40 of the FOIA (personal data)] presented an update on the BP digital project. A paper was brought to CET in April, and a commitment was made to return to CET with a more specific proposal of the foundation of work and resource required in the first year of the project. In the initial 12 months of the first phase, the proposal is to start to develop the in-house capacity, capability and knowledge required to fully understand the feasibility of insourcing marketing of the BP publication. The proposal consists of 2 parts – firstly to collate and interrogate the BP publication data to form a conclusion to the feasibility study; and building capacity by undertaking market research and marketing activities for the BPCRS business to build the necessary capability within the agency to complete the feasibility project, and additionally to increase sales. The work will be monitored by the steering group and will report back to CET with future progress updates. The CET thanked [name redacted under section 40 of the FOIA (personal data)] for the paper and agreed to a 1-year fixed term post for this work.

7. Operational Excellence (CET/17/158)

7.1 [Name redacted under section 40 of the FOIA (personal data)] presented an update about the Operational Excellence Steering Group. The steering group has been in existence since early 2011; the group have overseen the training of staff in Lean Six Sigma and delivery of projects using this methodology. It was recognised that there has been a challenge for trainees to deliver projects and put time in to implementing their learning from Lean Six Sigma; however there have been some notable successes. The steering group have recognised the need to review where it fits in the corporate governance structure, in line with the Digital and Operational Transformation programme of work. The proposal was made to review the operational excellence role and provide an update to CET once the case for Operational Transformation has been better understood.

7.2 The CET acknowledged the value that Lean Six Sigma has given to the Agency across all the divisions. The CET agreed to undertake a review of the Operational Excellence steering group's role and the role of continuous improvement as part of Operational Transformation programme, including terms of reference and membership of the group. It was agreed that in flight projects continue through to completion, unless there is a decision made by the steering group to stop a project; and to provide an update to CET in due course.

Action: Review role of operational excellence steering group in relation to the Operational Transformation programme; and bring back to CET.

8. Operational Transformation Update (CET/17/178)

8.1 [Redacted under section 35 of the FOIA (Formulation of government policy)]

GOVERNACE & DELIVERY

9. Overtime Policy (CET/17/157)

9.1 Jon Fundrey presented the updated overtime policy. The Overtime Policy was being reviewed as part of the ongoing process to review all HR Policies and with parallel issues

and concerns relating to use of overtime, the opportunity is being taken to discuss past practice and future plans. Currently there is a lack of consistency regarding overtime across the Agency. The CET noted that in relation to rates of pay for overtime, there are nationally negotiated civil service rates of pay which the Agency adheres to. All arrangements of overtime should be agreed in advance. The CET endorsed the new policy which will be published with a communication to staff on insite.

10. Annual report 2016/17 (CET/17/160)

10.1 Rachel Bosworth presented an updated draft of the Annual Report for 2016/17, which the CET noted and gave comments on. Subject to proofing this copy is ready to be sent to the Agency Board; the CET were urged to send any comments on this to Comms by Tuesday 13th June.

11. Quarterly/Annual Special Bonus – 2016/17 (CET/17/161)

11.1 Vanessa Birchall-Scott presented a report on bonuses awarded in the fourth quarter of 2016/17. The CET noted that in the first three quarters the Agency fell short of the ceiling of special bonuses, however in last quarter the Agency has exceeded the annual allowance. A mechanism will be put in place for future to mitigate any future risks and monitor the allocation of special bonuses. The CET were presented with statistics on the demographics of the staff members allocated bonuses; all the statistics are reviewed by the subgroup of the Equality & Diversity group. In future reports on special bonuses the demographics will be integrated more in to the reporting. Future reporting will also include the voucher scheme and SCS bonuses. It was noted that each bonus application is seen by the leadership teams and is signed off by HR business partners, who could have a role in monitoring the number of bonuses to ensure the limit is not exceeded in future.

12. Annual pay calculations (verbal) (CET/17/162)

12.1 Vanessa Birchall-Scott presented a proposal of pay calculations for the next year. The CET discussed the pay proposals and selected the most suitable option which will be further discussed at the pay committee meetings.

13. Board/CET away day draft agenda (CET/17/163)

13.1 Ian Hudson presented the draft agenda for the Board/CET away day. The next of the Agency's six-monthly Board/CET away days will take place on Tuesday, 25 July at the Royal Society in central London. The proposed programme covers the topics (i) Brexit, (ii) the next Corporate Plan, (iii) Operational Transformation, and (iv) the regulation of software, apps and artificial intelligence. The CET agreed the draft agenda.

14. Corporate Risk Register (CET/17/164)

14.1 Jon Fundrey and [name redacted under section 40 of the FOIA (personal data)] presented the Corporate Risk Register. There were 10 red risk items, with 2 new risks: the threat of NIBSC's data loss as IT operations are not yet integrated with Agency's systems and recent cyber-attack; and the failure to comply with General Data Protection Regulation (GDPR). The CET provided comments and updates to the CRR.

15. NIBSC Q4 Report to SMT

15.1 Ian Feavers presented the NIBSC Q4 report. With regards to recruitment, the 3 posts in the senior management team have all now been filled. The horizon scanning post has also

been filled however this is still currently being negotiated. The KPI for turnaround time of batch release was achieved for the year, successfully meeting the 99% target for releases within the specified number of days. Standards sales in flu and non-flu standards were strong throughout the year. The target turnaround time of 93% of materials shipped within 6 working days was again achieved in Q4 at a level of 96%, but due to the resource problems in the first two quarters, the KPI for the full year was not achievable.

15.2 Within the year, the SMT reviewed the role of the Programme Boards to look at how they have been running and if this structure and use of the Boards has been effective. The review found they fulfil a valuable function and provided useful feedback in how they operate. 7 new standards have been endorsed by the Expert Committee on Biological Standardisation. NIBSC has reached the end of the financial year in a healthy position. NIBSC underwent its third investment round during the year and agreed to some new posts in areas across NIBSC. The CET noted the successes of the last year and thanked Dr Feavers for the update.

16. Agreement of team briefing notes

16.1 The items appropriate for circulating to staff as team briefing were agreed by the CET.

INFORMATION

17. NIBSC SMT Briefing paper (CET/17/167)

17.1 The NIBSC SMT Briefing paper was noted.

18. Draft minutes of the 23 May Regulatory Group meeting & final minutes of the 25 April Regulatory Group meeting (CET/17/169)

18.1 The draft minutes of the 23 May Regulatory Group meeting and the final minutes of the 25 April Regulatory Group were noted.

19. Updates from Cross-Agency teams

19.1 These updates were noted by the CET:

Information Management Governance Board (IMGB)	CET/17/170
Finance Sub Committee meeting	CET/17/171
Audit and Risk Assurance Committee	CET/17/174
Risk and Audit Liaison Group	CET/17/175
Equality and Diversity Group	CET/17/176

20. Agreement of 11 July 2017 CET agenda (CET/17/177)

20.1 The CET agreed reviewed and commented on the draft agenda for the 11 July CET meeting. It was agreed that a number of items had still to be confirmed; relevant directors would advise Directorate.

21. AOB

None.