Medicines & Healthcare products Regulatory Agency

Minutes (FINAL)

Title of meeting	Corporate Executive Team formal monthly meeting
Date	05 May 2016
Time	08.30 – 13.00
Venue	R-T-410, BPR
Chair	Ian Hudson
Attendees	CET
Apologies	Peter Commins, Mark Wilson

CET Attendees

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

Additional attendees

[Names redacted under section 40 of the FOIA (personal data)]
Patience Wilson (Policy) for item 12: Fraud governance and awareness raising and item 9: Conflicts of Interest policy

1. Apologies and Announcements

1.1 Apologies were received from Mark Wilson; Anne Paskin attended in his absence. Apologies were received from Peter Commins; [Name redacted under section 40 of the FOIA (personal data)] attended in his absence and Richard Humphreys joined the meeting from 12pm.

2. Draft minutes of the 5 April Corporate Executive Team meeting (CET/16/114) including table of actions and final minutes of the 10 March Corporate Executive Team (CET/16/115)

2.1 The draft minutes of the 5 April meeting were agreed with minor updates. The CET reviewed, and provided updates on, the table of actions. The final minutes of the 10 March meeting were noted.

3. Draft minutes of the Agency Board of 11 April (CET/16/116) and final minutes of the 14 March Agency Board (CET/16/117)

3.1 The draft minutes of the 11 April Agency Board and the final minutes of the 14 March Agency Board meeting were noted.

STRATEGY

4. Organisational transformation: next steps following 22 March (CET/16/118)

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

5. Annual Pay Guidance, Policy and Flexibility Options, 2016 (CET/16/119)

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

GOVERNANCE & DELIVERY

6. H&S full year report (CET/16/120)

6.1 Christian Schneider presented the Agency Health and Safety (H&S) full year report to CET. It was noted that in general H&S objectives were on track during the year. There have been several changes in terms of structure of the H&S team which has completely changed during the year. In addition Christian Schneider has now taken over the role as Health & Safety Champion for the CET from Stephen Inglis at the end of this reporting year. The report contains a detailed appendix with action plans.

6.2 The Health and Safety Executive (HSE) review of NIBSC safety performance using OHSAS (Occupational Health and Safety Management Systems) requirements showed that NIBSC have been 'broadly compliant' over the last year; however this requires further review for the next year. NIBSC best practice risk assessments were at 100%. The audit of BPR raised 2 minor corrections however finalised with a good result. Health and Safety policies were developed over the last year which have now all been seen by the CET. In relation to training and competency; there are some civil service learning modules staff are required to undertake which was demonstrated in the report; for example driving monitor for those who drive on Agency business. In relation to incidents and accident reporting; there were only a few minor accidents which did not need reporting to the HSE. There were 2 incidents that required reporting — however risk assessments were performed after these and lessons learnt, and staff training was undertaken.

6.3 Accidents data trends showed increased reporting for NIBSC and MHRA; this was assessed to be due to increased access to software for reporting, and due to higher awareness; however this will continue to be reviewed. A number of strategic items were noted; including improved access to staff for information, and advice and support for staff related to travel. The overseas travel group has oversight of this.

6.4 The CET thanked Dr Schneider and [Name redacted under section 40 of the FOIA (personal data)] for the report and praised the clarity and level of detail. CET questioned whether it was in MHRA remit to undertake health and safety reviews of supplier accommodation. It was noted that this was picked up as part of the British Standards audit; however this will be investigated further by the H&S team. CET asked how long the Agency is tied in to the current driving contract with driving monitor and heard that we are contracted for another year. CET agreed that the Agency non-executive directors should not be included for driving assessments. The CET raised an issue with the proportionality of Agency health and safety policies overall, and asked the H&S group to continue to reflect on this.

Action: review requirements to undertake audits on supplier accommodation H&S group with head of facilities and estates.

7. Finance and Procurement Report (CET/16/121)

7.1 [Name redacted under section 40 of the FOIA (personal data)] presented the monthly Finance and Procurement report for the month of April and for the whole of the 2015/2016 financial year. The CET noted the agency's total operating surplus for the year to 30 April of £17.3m against a budgeted surplus of £18.0m. The operating surplus comprised £9.3m, £6.3m and £1.7m for the regulator, NIBSC and CPRD respectively. The NIBSC surplus is due to the additional income of approximately £1m from the flu standards work, and under spend on staff costs by around £2m. The cash position at 30 April stood at £207.6m. The Agency's retained surplus was £10.3m which was £0.2m under variance.

7.2 The CET noted that the operating income for the Agency was £160.3m, which is £6.3m above budget. Total operating costs were at £143.0m, which is £0.7m below budget. The number of full-time equivalent staff in post in March 2016 was: 1,252, with 166 staff on short-term contracts and 43 non-payroll employees. Capital expenditure at the end of March was £8.2m, while the total product licensing deferred revenue at the end of January was £18.8m.

7.3 The cash report demonstrates a decrease from September 2016, which is due to the super dividend to DH. The asset life of BPR was shortened to the end of December 2017 which was reflected in the report. The impact of pharmacovigilance fees on the period fee needs review now it is in more of a steady state.

8. Business Plan targets and strategic activities Q4 (CET/16/122)

8.1 [Name redacted under section 40 of the FOIA (personal data)] presented the Q4 Business Plan targets and strategic activities paper. In summary, the Agency met 33 of its 36 targets for 2015-16. Two targets were not met – increasing CPRD coverage of primary care data to 20% by the end of the financial year; and to enable 280 CPRD research studies in 2015/16. CET noted that the metrics for CPRD require rebaselining to more realistic targets. One target, to assess 97% of DCP RMS MA applications within 70 days, was nearly met. CET noted that this was due to understaffing of Licencing division.

8.2 Of the 78 activities due to be completed, 70 were completed and 8 were postponed; 6 of these postponed were due to factors outside of the Agency's control. In relation to metrics, the data was comparable to the previous year. CET noted that on metric 14, the 2 falsified medicines found in the supply chain did not make it to patients; a comment will be added to the document this effect. 3 out of 4 activities of further performance related work were completed; the unmet activity related to exploring possible means of measuring the impact of certain aspects of devices work and seek to develop some meaningful metrics; however CET agreed that a further update will be given on this as work has progressed on this topic. CET noted the very productive year overall.

Action: update metric 14 to reflect the fact that the falsified medicines found in the supply chain did not reach patients; and review further performance related work for an update on devices.

9. CoI policy (CET/16/123)

9.1 Patience Wilson presented the updated Conflicts of Interest (CoI) Policy to the CET. The CET reviewed the CoI policy at the December meeting and requested some revisions in relation to financial COI (and the issues raised last autumn around the DECIDE study); current activities carried out by CPRD; and the role of the CEO in the CoI process. This new policy has been signed off by Martin Hindle. The CET adopted the new policy and noted that it should be taken to the next Agency Board meeting for info.

Action: share the CoI policy with the Agency Board

10. NIBSC quarterly report (CET/16/124)

10.1 Christian Schneider presented the NIBSC quarterly report. The CET noted the Report and in particular the performance against the objectives in the agency's business plan as well as the performance measures that are monitored by the NIBSC SMT. The key achievements in the last quarter and the main priorities for the next period were also noted by the CET. CET noted in particular the great performance on

standards and the expenditure regarding the work done to attract companies to use NIBSC as their OMCL. A longer term presentation of grant income should be presented as the paper showed a fall compared with the previous year. CET also noted that the new synergies across the organisation should be explored and exploited.

Action: NIBSC to review grant trends and synergies across the organisation.

11. SSFFC project with WHO (CET/16/125)

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

Action: Continue with project progression, and draft update to CMO

12. Fraud governance and awareness raising (CET/16/126)

12.1 [Name redacted under section 40 of the FOIA (personal data)] presented a paper to CET on fraud governance and raising awareness. CET were asked to decide whether there should be one overall lead for all fraud as suggested by ARAC , and if so who; or to have another lead for non-regulatory fraud. CET noted that they were keen to maintain the responsibility of regulatory fraud with the operating divisions. It was agreed that Jonathan Mogford would take the lead for non-regulatory fraud. Gerald Heddell was nominated as the director to take oversight of regulatory fraud, recognising that each individual operating team has its own responsibilities for identifying and dealing with regulatory fraud. In relation to falsification of information for CPRD or NIBSC, this would be considered regulatory fraud; whereas financial fraud would fall under other fraud.

13. Annual Report (CET/16/127)

13.1 Rachel Bosworth presented the updated draft annual report, with overview information presented in a more appropriate format. The CET agreed that the report is coming together very nicely; and noted a few minor changes to be made. The draft report is being presented to the Agency Board at the next meeting and the final version will brought back to CET and the Board in June.

14. Devices transformation business case (CET/16/128)

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

15. Accommodation update (CET/16/143)

15.1 [Redacted under section 43 of the FOIA (Commercial interests)]

16. Agreement of team briefing notes (CET/16/129)

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

17. Corporate Risk Register review (CET/16/144)

17.1 Richard Humphreys presented the agency's Corporate Risk Register (CRR), which was last seen by CET on 8 December and will be seen by the Audit and Risk Assurance Committee (ARAC) in June.

17.2 The CET agreed the new or revised text proposed in risks 1, 2, 3, 5, 6, 8, 9, 10, 11, 18 and 20. Risks 7, 12 and 14 should be removed and kept on the divisional risk registers. Product names should be removed from all the risks.

Action: F&P to update the CRR to reflect CET's comments and submit to ARAC for discussion for the June meeting

INFORMATION

18. NIBSC SMT update (CET/16/130)

17.1 The CET noted the notes from the April NIBSC SMT meeting.

19. Draft minutes of the 19 April Regulatory Group meeting (CET/16/132) and final minutes of 23 March Regulatory Group (CET/16/133)

18.1 The final minutes of the 23 March meeting and the draft minutes of the 19 April meeting were noted.

20. Updates from Cross-Agency teams

19.1 These updates were noted by the CET.

Information Management Governance Board (Mar. 2016 final)	CET/16/134	Peter Commins
Information Management Governance Board (Apr. 2016 draft)	CET/16/135	Peter Commins
Finance Sub Committee meeting (Dec. 2015 final)	CET/16/136	Peter Commins
SOP Working Group (April 2016 draft)	CET/16/137	Gerald Heddell
Health and Safety Strategy Group (March 2016 draft)	CET/16/138	Christian Schneider
Audit and Risk Assurance Committee (March 2016 draft)	CET/16/139	Peter Commins
Risk Management & Audit Liaison Group (April 2016 draft)	CET/16/140	Peter Commins
Equality and Diversity Group (April 2016 draft)	CET/16/141	Vanessa Birchall-Scott

21. Agreement of 14 June CET agenda (CET/16/142)

20.1 The CET agreed the agenda for the 14 June meeting.

22. AOB

None.