Medicines & Healthcare products Regulatory Agency

Minutes (final)

CET/17/126

Title of meeting	Corporate Executive Team formal monthly meeting
Date	3 March 2017
Time	09.00 – 13.00
Venue	501-2, BPR
Chair	Ian Hudson
Attendees	CET
Apologies	June Raine, Christian Schneider

CET Attendees

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

Additional attendees

Andy Gregory (Policy) for items 4: Brexit – update and discussion (verbal) and 5: International Strategy
Samantha Atkinson (IE&S) for item 5: International Strategy
Mick Foy (VRMM) for items 5: International Strategy and 6: Patient Safety & Vigilance Strategy
Tony Sant (Devices) for item 6: Patient Safety & Vigilance Strategy
[Name redacted under section 40 of the FOIA (personal data)] for item 7: Falsified Medicines and Medical Devices campaign - update
Richard Humphreys (F&P) for items 8: Budget 2017/2018, 13: Quarterly Review of the Agency's Corporate Risk Register and 15: Procurement and Contract Management Audit Response
Patience Wilson (Policy) for item 9: 2017/18 Business Plan
[Name redacted under section 40 of the FOIA (personal data)] for item 11: Health and Safety Full Year Report
Joe Kyne (IE&S) for item 14: Agency's External Fraud Risk register

[Name redacted under section 40 of the FOIA (personal data)] for item 15: Procurement and Contract Management Audit Response
[Name redacted under section 40 of the FOIA (personal data)] for item 16: Annual Lecture 2017

1. Apologies and Announcements

1.1 Apologies were received from June Raine, Christian Schneider and Jon Fundrey.

2. Draft minutes of the 1 February Corporate Executive Team meeting (CET/17/058) including table of actions and final minutes of the 13 January Corporate Executive Team meeting (CET/17/059)

2.1 The draft minutes of the 1 February meeting were agreed. The CET reviewed and provided updates on the table of actions. The final minutes of the 13 January meeting were noted.

3. Final minutes of the 12 December 2016 Board meeting and note of the Board/CET away day on 27 January 2017 (CET/16/060)

3.1 The final minutes of the Board meeting of 12 December and the note of the Board/CET away day on 27 January 2017 were noted.

STRATEGY

4. Brexit – update and discussion (verbal) (CET/17/061)

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

5. International Strategy (CET/17/062)

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

6. Patient Safety & Vigilance Strategy (CET/17/063)

6.1 Mick Foy and Tony Sant presented an update on the ongoing work on the Patient Safety and Vigilance Strategy (PSVS), since the last update at CET in October 2016. Project team 1 have been looking at incident reporting and signal detection; signal detection analysis on devices data is ongoing and a report is expected in May. The mobile reporting app is up and running; under IMD and GDS advice, consideration is being given to switching the platform for mobile reporting away from an app to more mobile responsive technologies. Work has begun on developing a standard reporting form for devices incidents, in line with e2b standards for ADR reporting.

6.2 Project team 2 have been working on risk benefit assessment; PSUR development has been ongoing; dependant on Brexit, this is something which the UK could continue outside of the EU system. Feasibility studies have been ongoing in to using CPRD for signal detection and strengthening; this is making good progress. Project team 3 have been looking at improving delivery, targeting and audit of safety messages and risk communication; work is underway to develop a joint devices and Drug Safety Update (DSU) bulletin. An approach has been agreed to send electronic Dear Healthcare Professional Communications (DHPCs). A planning meeting has been held in the run up to the Health Summit planned for 5 June 2017, with other healthcare partners; discussions have been ongoing in to how to unify the sending of safety messages, with a common look and common prioritisation

system. It was noted that this overlaps with the ongoing CAS redevelopment work so will link in with this work.

6.3 Resourcing of the project was discussed; a new project management structure will be arranged, with Louise Loughlin working as PSVS programme management, supported by 2 existing project officers in her team who are currently working on the SCOPE project, due to end soon. Project Team 3 has recruited a delivery manager (0.6 G7). Project Team 1 has considered and decided against recruiting additional resource at this stage in the strategy. Additional resource in Project Team 2 is under consideration.

6.4 A mapping exercise was undertaken to analyse the similarities and differences in signal assessments in the medicines ad devices areas. Project team 2 undertook this analysis, mapping various processes and methodologies of signal management and signal assessment. A number of areas of commonality were identified; and in addition to this, the key differences were defined, including collective decision making and prioritisation, writing of signal assessment reports, and differing criteria for seeking expert advice. It was identified that a thorough SOP will be needed for future use. Further review of the differences in transparency of information and difference in how the departments monitor outcomes is merited. A programme is underway in Devices with IMDRF to develop terminology for adverse reporting to improve the quality of devices data.

6.5 The CET noted the value of the work of the PSVS. It was noted that CPRD have been contributing resources to understand how CPRD can be used for medical device safety; the new Head of Observational Research will be working on this when they join the Agency. A paper from CPRD is underway to review outcomes for patients with metal-on-metal (MOM) hips compared with non-MOM hips. It was noted that the DHPC pilot should be linked in with the revamp of the CAS system. The CET endorsed the paper, gave support for the project to continue as proposed; and noted that work should continue to explore and potentially align the areas where there are differences between medicines and devices.

GOVERNANCE & DELIVERY

7. Falsified Medicines and Medical Devices campaign – update (CET/17/067)

7.1 [Name redacted under section 40 of the FOIA (personal data)] presented an update on the falsified medicines and medical devices campaign. An evaluation of activity to date shows that the campaign has had a positive start and made a significant impact on its agreed objectives since the launch on 16th August 2016. It is estimated that over 30 million individuals have been reached in the UK, and there has been a 10% increase in the perception of buying products online. A schedule of sustained communications activity is planned to support ongoing delivery across 2017/18. This will introduce additional prioritised product waves and continue to focus on those from phase one. In line with Cabinet Office requirements, a business case has been developed to support the next year of the campaign, which will need approval at Ministerial level for a total of £387,000. Spend will be on PR and media, with further investment in partnership work to reap return through sponsorship; and online and offline advertising.

7.2 One key proposals of the strategy is the planning and implementation of a documentary marking the ten year anniversary of Operation Pangea and the enforcement work of the Agency. CET were asked for approval to continue with the proposed documentary. CET noted the potential downsides of the documentary but noted that the benefits of increased awareness outweigh any risks; and endorsed participation in the documentary.

Action: Participate in the Operation Pangea documentary; take forwards business case; take this paper to Agency Board in April 2017.

8. Budget 2017/2018 (CET/17/068)

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

9. 2017-18 Business Plan (CET/17/091)

9.1 Patience Wilson and [name redacted under section 40 of the FOIA (personal data)] presented the draft 2017-18 Business Plan. The draft was circulated to CET members for comments. The business plan has been drafted following previous comments to include shorter, sharper more strategic priorities. The CET noted that more achievements should be included from operational divisions in the plan; the top 10 priorities should be prefaced by noting the Agency's routine work that protects and improves public health. The business plan will be presented to the Agency Board at the 17 March meeting.

10. People Survey Action Plans (CET/17/069)

10.1 Vanessa Birchall-Scott presented an update on the people survey action plan. The CET were given an opportunity to review and comment on the draft pan-Agency and division/centre People Survey action plans. Three priority-related People Survey targets were proposed, in relation to my manager, bullying and harassment, and visibility of senior leaders. For the pan-Agency action plan, the CET noted that this includes actions for CET directors and for managers; which should be included alongside progress against divisional action plans. The HR business partners will be available to support initial planning discussions at divisional SMT meetings. It was proposed that the People Survey Focus Group should be refreshed; with an opportunity for staff to rotate from divisions in to this group.

10.2 The CET noted that the Agency's ambition is to see an improvement in the scores of the proposed targets, in response to actions taken in each of the three areas. The CET also endorsed the refresh of the focus group.

11. Health and Safety Full Year Report (CET/17/070)

11.1 [Name redacted under section 40 of the FOIA (personal data)] presented the Annual Health and Safety Report 2016-17. Good progress has been made against agreed targets even though there have been significant staff changes in the H&S Team (a completely new team is now in place since October 2016). Where delays were experienced, a plan was put in place to prioritise outstanding objectives. The Agency has maintained certification to OHSAS 18001 at Buckingham Palace Road and the high containment staff and facilities at NIBSC have received positive feedback following HSE inspections.

11.2 Two incidents were reported to the HSE under RIDDOR (Reporting of illnesses, Diseases and Dangerous Occurrences regulations). The HSE investigated the second incident and were satisfied with the internal investigation findings and recommendations. An enforcement letter will be sent following this investigation which will require a formal response to the actions stated by the HSE.

11.3 The CET noted that a number of the KPIs have not been met; for example some safety training course targets have not been met as some staff did not complete the training course properly. It was noted that there is a wider issue relating to recording of training data

which is a contributing factor. All CET members should take an action to review which of their staff need to undertake the mandatory training courses. In relation to overseas travel, the policy is being worked up for the Agency – IE&S is where highest risk is due to overseas inspections. Significant resource will be required for this in the next few years; training will be required for high risk travellers. Further detail should be included in the paper to ARAC on how the Agency will tackle the issues discussed.

Action: CET members to identify which of their staff need to undertake mandatory safety training courses. Include additional detail in ARAC paper. Extend the H&S work on overseas travel.

12. Agency Risk Appetite statement (CET/17/071)

12.1 Jon Fundrey and Richard Humphreys presented the Agency's Risk Appetite statement, which was previously discussed at the CET MAD session in February 2017. CET gave drafting comments to the statement, in relation to proportionality, cautiousness, and taking in to account the circumstances in order to achieve the Agency's' statutory objectives and protect public health.

13. Quarterly Review of the Agency's Corporate Risk Register (CET/17/072)

13.1 Richard Humphreys presented the CRR, which the CET reviewed. There was an increase in the Brexit risk. New risks on the CRR were discussed; in relation to provision of data, and recruitment and retention. CET provided comments and updates on the risks; the CRR will be presented at the upcoming ARAC meeting on 17th March.

14. Agency's External Fraud Risk Register (CET/17/073)

14.1 [Name redacted under section 40 of the FOIA (personal data)] presented the Agency's External Fraud Risk Register. ARAC asked for an analysis of the Agency's resilience at discovering and managing attempts to disregard or bypass due regulatory process for illegal gain. The paper presented a summary of where regulatory fraud could occur; including misleading data; failure to notify the Agency of changes to licences and product specifications; and attempts to infiltrate the legal supply chain with substandard products for illegal gain. 2 areas were identified where action has been taken; and a number of case studies were drawn up in the paper to demonstrate actions that have been taken. The legal supply chain investigation was also included in the paper.

14.2 It was noted that the MHRA will need to maintain a constant watch to identify any changes to patterns of fraud which exist; the intelligence unit does asses these patterns of fraud for this reason.

14.3 The CET noted that having identified the risks, more training may be required for staff. The regulatory fraud risks apply to all of the operating divisions in the Agency and should form part of assessor's training programmes. An action was taken to ask operational teams to consider whether there are additional areas in which training could be given in terms of regulatory fraud. The operating divisions should consider the fraud risk register in this paper; and inform the authors of mitigations in place to counteract fraud.

Action: Operational teams to consider whether there are additional areas in which training could be given in terms of regulatory fraud.

15. Procurement and Contract Management Audit Response (CET/17/074)

15.1 [Name redacted under section 40 of the FOIA (personal data)] presented the response to the procurement and contract management audit. The Agency has recently been subject to a contract management audit. The review identified a number of significant control weaknesses, both with the design of controls and non-compliance with existing procedures in conjunction with contract management. The overall audit rating was "Unsatisfactory"; therefore a number of recommendations were made to address this. The Agency accepted all of the report's recommendations. The FSC group will be used to implement the audit recommendations across the Agency. A number of new and revised policies and procedures will need to be produced especially around contract management. The CET agreed to address this and adopt commercial standards going forwards. It was also noted that this should be added to the Agency's Risk Register.

Action: Add to the Risk Register; take forward the recommendations in the audit response.

16. Annual Lecture 2017 (CET/17/075)

16.1 [Name redacted under section 40 of the FOIA (personal data)] presented the arrangements for the Agency's 2017 Annual Lecture. The Annual Lecture 2017, titled "Disease knows no borders: why global health must survive political upheaval", will be delivered by Dr Jeremy Farrar OBE, Director of the Wellcome Trust on 26 May 2017, at the Francis Crick Institute. The CET endorsed the plans for the annual lecture.

17. NIBSC Quarterly Update Report (CET/17/076)

17.1 Ian Feavers presented the NIBSC Quarterly Update Report. CET noted that most objectives remain on track at the end of Q3. In relation to the performance KPIs; 2 batches of immunoglobulin out of 1500 failed to meet the turnaround time; however this is well within target with a result of 99.87% against target. There has been a major update to CTLIMS to remove some bugs; the objective in relation to the benefits of CTLIMS is expected to be met in the next year. 3 PhDships have been awarded for the next year, which have been agreed by the CET. There has been good progress made with flu standards preparation this year. Recruitment of 3 out of 7 scientific division positions has been completed. The CET noted the update and congratulated NIBSC on the work which has been undertaken so far this year.

18. Finance and Procurement Report (CET/17/077)

18.1 Richard Humphreys presented the Finance and Procurement report for the first 10 months of the financial year. After allowing for Dividends and Financing, after nine months of the year the Agency has a retained surplus of £5.2m which is £4.0m above budget. The Agency is forecast to deliver a retained surplus in 2016/17 of £9.8m which is £3.3m above budget; the CET should note that the forecast expenditure of ICT is being continually reviewed. The CET noted the update.

19. Agreement of team briefing notes

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

INFORMATION

20. CPRD SMT Partners Meeting Minutes (CET/17/079)

20.1 The CPRD SMT Partners Meeting Minutes were noted.

21. NIBSC SMT report (CET/17/080)

21.1 The NIBSC SMT report was noted.

22. Draft minutes of the 21 February Regulatory Group meeting & final minutes of the 17 January Regulatory Group meeting (CET/17/081)

22.1 The draft minutes of the 21 February Regulatory Group meeting and the final minutes of the 17 January Regulatory Group were noted.

23. Updates from Cross-Agency teams

23.1 These updates were noted by the CET:

Information Management Governance Board (IMGB)	CET/17/082
Finance Sub Committee meeting	CET/17/083
Policy and Procedures Committee	CET/17/084
Audit and Risk Assurance Committee	CET/17/086
Risk and Audit Liaison Group	CET/17/087

24. Agreement of 11 April 2017 CET agenda (CET/17/090)

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

25. AOB

None.