Medicines & Healthcare products Regulatory Agency

Minutes (final)

Title of meeting	Corporate Executive Team formal monthly meeting
Date	12 July 2016
Time	09.00 – 13.00
Venue	G3, BPR
Chair	Ian Hudson
Attendees	CET

CET Attendees

Ian Hudson	Chief Executive (Chair)
Richard Humphreys	deputising for the Chief Operating Officer and Director of Finance
Rachel Bosworth	Director of Communications
Christian Schneider	Director of National Institute for Biological Standards & Control
Jonathan Mogford	Director of Policy
Gerald Heddell	Director of Inspection, Enforcement and Standards
[Redacted]	deputising for Director of Human Resources
Liz Baker	deputising for the Director of Licensing
John Wilkinson	Director of Devices
John Quinn	Director of Information Management
June Raine	Director of Vigilance and Risk Management of Medicines
[Redacted]	deputising for the Director of the Clinical Practice Research Datalink
Mark Wilson	DH Legal Services

Additional attendees
[Names redacted under section 40 of the FOIA (personal data)]

1. Apologies and Announcements

1.1 Apologies were received from the following CET members Vanessa Birchall-Scott, Peter Commins, Siu Ping Lam, Janet Valentine, as well as [name redacted under section 40 of the FOIA (personal data)]..

2. Draft minutes of the 14 June Corporate Executive Team meeting (CET/16/178) including table of actions and final minutes of the 5 May Corporate Executive Team (CET/16/179)

2.1 The draft minutes were agreed. The CET reviewed and provided updates on the table of actions. The final minutes of the 5 May meeting were noted.

3. Draft minutes of the Board meeting of 17 June 2016 (CET/16/180) and final minutes of 9 May (CET/16/181)

3.1 The draft minutes of the Board meeting of 17 June were noted, while the final minutes of the Board meeting of 9 May were noted.

STRATEGY

4. Post EU Referendum – update and discussion (CET/16/182)

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

5. Interim Report on Clinical Trial (CET/16/183)

5.1 [Redacted under section 27 of the FOIA]

News, Digital and Content Strategy (CET/16/184) – deferred to the CET meeting on 9 August

6. Customer Services Strategy (CET/16/185)

7.1 [Name redacted under section 40 of the FOIA (personal data)] presented an update on the work of the Customer Services Strategy Group, which included a proposed strategy for taking forward customer service across the Agency. The CET heard that customer service cuts through all aspects of the Agency's business and that the Agency needs to focus on greater cross-agency work and provide a joined-up, seamless service for the Agency's customers. As part of this work, the Agency also needs to take advantage of the digital investment programme to improve these services and the customer experience. Accordingly, a new customer service strategy, backed by a comprehensive delivery plan, was proposed. [Name redacted under section 40 of the FOIA (personal data)] advised that this would sit at the heart of the Agency's ambitious long-term plans to improve operational excellence and to deliver the Agency's public health priorities. [Name redacted under section 40 of the FOIA (personal data)] then went on to outline the three main components of the paper under the following headings: 'where we are now', 'where we want to be' and 'how we are going to get there'. The latter included four recommendations to the CET, which included a request to approve a staff resource for the initial project management work.

7.2 While welcoming the Customer Services Strategy and commending the team concerned for making such a positive start, the CET made two specific requests. The first concerned the wording of the vision, which the CET thought required further work to make the message more concise. Second, the CET thought the strategy was too focussed on industry, and should reflect the needs of other stakeholders as well, such as healthcare professionals/other organisations in the healthcare network. Additionally, the CET advised that, should there not be any doubt in the eyes of the reader that the strategy was for the whole agency and not only the regulator.

7.3 The CET then approved the vision (subject to some rewording offline), the approach set out at Section C, the alignment of governance and working groups, and the request for a staff resource with the initial project work.

Action: the vision section of the Customer Services Strategy to be revised to make it more concise.

7. Judicial Review on Glucosamine-containing products (CET/16/186)

8.1 [Redacted under Section 42 of the FOIA (Legal professional privilege)]

GOVERNANCE & DELIVERY

9. People Survey – action plans and updates (CET/16/187)

9.1 [Name redacted under section 40 of the FOIA (personal data)] presented an update on the 2016 People Survey and on the action plans from last year's People Survey. The CET heard a number of changes have been made to the questions that will appear in the 2016 Survey; these reflect feedback received following last year's exercise. The Agency has decided not to add further agency specific questions to this year's survey. As for the 2015 People Survey action plans, both divisional and pan-agency action plans have been updated and are now available on INsite. The CET welcomed the update, noted the

progress made against the divisional and pan agency action plans and approved the plans for the 2016 People Survey.

10. Falsified Medicines and Medical Devices communications campaign update (CET/16/188)

10.1 [Name redacted under section 40 of the FOIA (personal data)] presented a paper on the falsified medicines and medical devices (FMD) campaign, which included suggested changes following the EU referendum result on 24 June. After the Referendum, [name redacted under section 40 of the FOIA (personal data)] and other colleagues assessed different aspects of the FMD campaign to identify which areas were most affected. The assessment was also informed by guidance from Cabinet Office to government bodies. The CET heard that the aspect of the campaign most affected was the 'call to action'. The call to action focuses on two areas: reporting falsified products and signposting towards legitimate products. The CET heard that the latter poses a challenge, as the campaign's signposting involved messages that reinforce EU legislation around the medicines supply chain. The three key affected areas are: (i) EU Common Logo, (ii) CE Marking, (iii) legitimate supply chain measures.

10.2 [Name redacted under section 40 of the FOIA (personal data)] reported that the 'call to action' would be edited so that the signposting section does not explicitly reference the EU, while still giving the target audience and innovative and accurate means of verifying retailer legitimacy. The CET heard that the language used in the campaign will be changed and the focus on the verification initiatives will be on highlighting the importance to the public, as opposed to drawing attention to them being developed as part of an EU Directive. This approach will allow schemes, such as the Common Logo, to be promoted as an important resource for the public. Additionally, the CET discussed the balance of the campaign, in particular, whether it would extend beyond slimming pills in phase 1 to cover erectile dysfunction (ED) tablets. [Name redacted under section 40 of the FOIA (personal data)] advised that ED products would be covered in year 2 of the three-year campaign, with STI self-test kits, dentistry equipment and condoms being covered first in year one.

10.3 Having considered the update and proposal, the CET endorsed an amended strategy, along with the revised campaign delivery schedule for year one (August 2016 – March 2017).

11. BP/NIBSC Herbal Project (CET/16/189)

11.1 [Name redacted under section 40 of the FOIA (personal data)] presented a progress report on the British Pharmacopeia/ NIBSC herbal project at NIBSC. The CET heard that the project, which started as a 'merger project' and was approved for expansion by the CET in April 2015, is progressing at a good rate. The molecular activities pursued at the BP-NIBSC Laboratory have evolved into close collaboration with academia and industry, and have produced tangible commercial outputs.

11.2 As part of his report, [name redacted under section 40 of the FOIA (personal data)] outlined the benefits gained from the project, current activities and outcomes future activities and increased capabilities. The latter included an update on a fully functioning chemistry laboratory at NIBSC which will be in place by September 2016. Additionally, the CET heard that the herbal; laboratory will apply for ISO9001 certification for which an implementation plan has been drafted and an advisory panel has bene assembled.

11.3 The CET welcomed the report and commended the team involved. Dr Hudson asked that a list of herbs covered by the project be included in the next report. Additionally, it was agreed that St John's Wort be included in the work programme; moreover, the next report, which come to the CET in July 2017, will have an appropriate governance style, and will not be for information only. The CET recommended that an article about the project be published on insite to highlight this innovative work to colleagues, with an external piece to follow later.

Action:
(i) BP/NIBSC herbal project report for July 2017 to include a list of herbs.
(ii) An article about the work of the project to be published on insite, with a similar article on the external website to follow later.

12. Revalidation Report (CET/16/190)

12.1 [Name redacted under section 40 of the FOIA (personal data)] presented the Revalidation Annual Report – A Framework of Quality Assurance for Responsible Officers and Revalidation. The Revalidation Framework was introduced in 2014 in order to provide a quality assurance required that the Responsible Officer and Designated Body are discharging their respective statutory responsibilities.

12.2 The CET considered the following documents:

(i) The third Revalidation Annual Report covering the period April 2015 to March 2016 (Responsible Officers are required to present an annual report to their board or management team)

(ii) The Annual Organisation Audit (AOA) (end of year questionnaire submitted to NHS England /Department of Health)

(iii) A Statement of Compliance, which should be signed off by the Chairman before 30th September and submitted to the higher level responsible officer (the Chief Medical Officer).

12.3 The CET heard that the revalidation process for MHRA's medics IN 2015/16 went very well. This has been borne out by the positive feedback about the appraisers. [Name redacted under section 40 of the FOIA (personal data)] concluded by reporting that Sir Alex Markham, Non-Executive Director, will succeed Professor Angus Mackay, as principal assessor for senior medics in the Agency.

13. Finance and Procurement Report (CET/16/191)

13.1 Richard Humphreys presented the monthly Finance and Procurement report for the month of December and for the first two months of the financial year. The CET noted the agency's total operating surplus for the year to 31 May of £2.8m against a budgeted surplus of £1.8m. The operating surplus comprised £8.0m, £0.7m and £0.3m for the regulator, NIBSC and CPRD respectively, less the corporate deficit of £6.2m. Following payment of dividends the overall retained surplus is £1.4m against a budget of £0.3m. The cash position at 31 May stood at £216.6m. The forecast surplus at year end after dividend of £7.8m was also noted. The CET noted the detailed income and expenditure accounts including the continuation of the significant expenditure variance on staff costs, which are now £200,000 (2%) below budget overall.

13.2 As part of his report, Mr Humphreys advised there were no immediate income effects from the outcome of EU Referendum, although that may change in the future. Mr Humphreys outlined areas where potential signs of income reduction could occur. Accordingly, the financial report's colour-coded dashboard would be revised to reflect the post-referendum environment.

14. Agreement of team briefing notes (CET/16/0192)

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

INFORMATION

15. NIBSC SMT update – deferred to August

15.1 The CET noted that the June meeting had been cancelled and that the minutes of the July SMT would come to the August CET.

16. CPRD minutes – deferred to August

16.1 The CET noted that the next meeting of the CPRD Executive Committee would be on 28 July.

17. Draft minutes of the 23 June Regulatory Group meeting (CET/16/193) and final minutes of 19 May Regulatory Group (CET/16/194)

17.1 The draft minutes of the 23 June meeting and final minutes of the 19 May meeting were noted.

18. Updates from Cross-Agency teams

18.1 These updates were noted by the CET.

Information Management Governance Board (4 May. final)	CET/16/0195	Peter Commins
June IMGB meeting was cancelled.		
Finance Sub Committee meeting (26 May final)	CET/16/196	Peter Commins
SOP Working Group (6 June. final)	CET/16/197	Gerald Heddell
Health and Safety Strategy Group (next meeting 2 September)		Christian Schneider
Audit and Risk Assurance Committee (June minutes are out for comment)		Peter Commins
Risk Management & Audit Liaison Group (next meeting 14 September)		Peter Commins
Equality and Diversity Group (next meeting 27 July)		Vanessa Birchall-Scott

19.Agreement of 9 August 2016 CET agenda (CET/16/198)

19.1 The CET agreed reviewed and commented on the draft agenda for the 9 August meeting.
It was agreed that a number of items had still to be confirmed; relevant directors would advise Directorate.

20.AOB

None.