Medicines & Healthcare products Regulatory Agency

Minutes (Final)

Title of meeting	Corporate Executive Team formal monthly meeting
Date	04 November 2015
Time	09.00 – 13.00
Venue	G3, BPR
Chair	Ian Hudson
Attendees	CET
Apologies	Peter Commins, June Raine, Jonathan Mogford

Ian Hudson	Chief Executive (Chair)
Richard Humphreys	deputising for Chief Operating Officer and Director of Finance
Rachel Bosworth	Director of Communications
Stephen Inglis	Director of National Institute for Biological Standards & Control
Patience Wilson	deputising for Director of Policy
Gerald Heddell	Director of Inspection, Enforcement and Standards
Vanessa Birchall-Scott	Director of Human Resources
Siu Ping Lam	Director of Licensing
John Wilkinson	Director of Devices
John Quinn	Director of Information Management division
Sarah branch	deputising for Director of Vigilance and Risk Management of Medicines
Janet Valentine	Director of the Clinical Practice Research Datalink
Mark Wilson	DH Legal Services

Additional attendees

[names of additional attendees for specific agenda items redacted]

1. Apologies and Announcements

1.1   Apologies were received from Peter Commins, Jonathan Mogford and June Raine. The Chief Executive welcomed [redacted] to the meeting as an observer. The aim is to give staff an understanding of how the agency's senior leadership team operates and how decisions are taken. A reminder was given that all meeting papers and discussions must be treated as confidential.

2. Draft minutes of the 13 October Corporate Executive Team meeting (CET/15/249) including Table of Actions) and final minutes of the 15 September Corporate Executive Team (CET/15/250)

2.1   The CET agreed the draft minutes of the 13 October CET meeting and noted the final minutes of the 15 September meeting.

3. Draft minutes of the Agency Board meeting of 16 October (CET/15/251) and final minutes of the Agency Board meeting of 18 September (CET/15/252)

3.1   The CET noted the final minutes of the 18 September Board meeting and the draft minutes of the 16 September meeting.

STRATEGY

4. Corporate Plan review and Business Plan 2016/2017 (CET/15/253)

4.1   [redacted] and [redacted] presented an update on the work to review the agency's Corporate Plan 2013-2018. The CET noted the summary of the 16 October Board discussion of the Corporate Plan review work. The Board endorsed the direction of travel and made a number of comments. These were being taken forward with the review work. It was agreed that in taking forward the next phase of the review, the CET would seek to develop its thinking on two substantive points made by the Board: (i) whilst there are clear synergies to exploit internally, what evidence is there that customers would see the agency's three centres as a USP?; and (ii) the strategy seems quite reactive – are we clear what vision we want to have?

4.2   The CET agreed the plan and timetable for taking forward the Corporate Plan review as well as the parallel work to develop the Business Plan 2016-2017. A key milestone identified in the plan is the Board/CET Awayday on 15 January 2016, at which the 'one siders' setting out the agency's proposed strategy in the key areas already identified, would be discussed and agreed.

4.3   The CET provided some comments on the diagram at Annex A, which sets out how the strategic focus fits together. It was agreed to include the agency's Financial Strategy and its Communications and Reputation Strategy within Theme 5, alongside the existing strategies on customer services, people and digital working. The CET agreed that the elements in the diagram could be represented in different ways, according to the audience. In certain circumstances it may, for example, be appropriated to place the agency's customers in the centre of the graphic, with the activities in the five Corporate Plan themes acting as key enablers to achieving customer satisfaction with the products and services that are offered. The CET agreed that the concept of 'business development' should be clearly defined in the context of the Corporate Plan review work. It was also agreed that the agency's USP should feed into the other external facing elements of the corporate plan, as well as being brought together with an appropriately defined business development. The CET thought that genomics might act as a specific example of an agency USP.

4.4   The CET commented on the composition of the cross-agency group tasked with further developing the Corporate Plan review and the parallel exercise on business planning. Directors agreed to review divisional membership of the CAG to ensure that it is equipped to drive forward this work.

Action: (i) directors and CAG to consider the two substantive points made by the Board; (ii) directors to review divisional membership of the CAG; (iii) Policy division to include the two additional strategies on finance and communications/reputation in the corporate plan

5. CPRD Strategic Direction (CET/15/254)

5.1   Janet Valentine presented the draft CPRD Strategic Plan 2016-2021 for agreement prior to presentation to the 20 November Board. The CET supported the work to implement the current and planned improvements, including on population coverage, data linkage, growing the intervention studies service, enhancing information governance and data security, working with the regulator, and developing partnerships. The CET endorsed the CPRD strategic objectives for the next 5 year period, as well as the detailed strategic activities proposed within each one.

5.2   The CET noted the updates on the development of key performance indicators, the CPRD staff restructuring exercise, and the financial model for the next 5 years. It was agreed to add further detail to the paper on: competition and risk referring to costs of IT developments; CPRD's key stakeholders; a more detailed sensitivity analysis of income; further information on the benefits of TrialViz. The CET also asked for the inclusion of some provisional targets for 2016/2017. The CET agreed the following: [Section 35 redaction: formulation of government policy]

Action: CPRD to update the Strategy to reflect the CET's comments and submit to the Board for discussion on 20 November

GOVERNANCE & DELIVERY

6. Horizon Scanning Group detailed report and next steps (CET/15/255)

6.1 [redacted] presented the second report of the Horizon Scanning Group (HSG). The CET heard that quarterly meetings of the HSG were held in January, April, July and October this year. Since the presentation of the first HSG report in May, a central repository of signals and other associated information has been created using Sharepoint/Office 365. Over 60 signal reports have now been generated and logged. These were noted by the CET. To date four areas of particular interest have emerged from the signals: [Section 35 redaction: formulation of government policy]

6.2 The CET strongly supported the work of the HSG and endorsed the need to think carefully about how to operationalise the signals generated. The question of additional secretariat resource was discussed and in particular, whether there would be any value added of appointing a specific resource to work as a bridge between the HSG and operational divisions, to ensure that signals are taken forward appropriately. The CET asked Licensing division and the Director of NIBSC to consider whether any additional resource might be located in association with Innovation Office. Any specific resource would be appointed on a pilot basis for perhaps 1-2 years, to better understand the extent to which additional administrative support was needed to operationalise signals. The pilot resource would be subject to business case approval. It was agreed to provide a paper to the Board once the next steps on how we are taking forward the recommendations – including the question of additional resource – had been progressed further.

Action: (i) Licensing division and NIBSC to explore whether any additional pilot resource might be located in the Innovation Office; (ii) NIBSC and Licensing division to reflect on the CET's comments about additional resources and make a proposal via the business case approval process; (iii) Horizon Scanning Group to recommend what steps need to be taken next in relation to the 4 areas of particular interest

7. NIBSC Quarterly Report (CET/15/256)

7.1 Stephen Inglis presented the NIBSC Quarterly Report covering the period 1 July to 30 September. This was noted by the CET.

8. Monitoring Report on Business Plan targets and activities Q2 (CET/15/257)

8.1 [redacted] presented the agency's 2015-2016 Business Plan Monitoring Report for Quarter 2. This included performance against targets, an update on the progress of strategic activities, a list of metrics for each of the last 4 quarters and a cumulative total for the 2015/2016 business year, and some information on further performance related work. The CET noted that the agency is on track to meet all of its published targets besides the following three: PM2(b)(c); PM7(b); and PM8(b).

8.2 For PM2(b)(c), the two elements of the target being missed (% DCP RMS in 70 days and Type IB % in 30 days) can be attributed to resource constraints. Recruitment of additional assessors is in progress. This, along with the expectation of a slight decrease in initial application volumes through Q3 and Q4, is likely to mean that the agency recovers performance against the DCP RMS target. For Type IB and Type II variations, however, this is likely to remain a challenge, as variation volumes are expected to remain at current levels despite the anticipated reduction in initial application volumes.

8.3 For PM7(b), as previously flagged at Q1, there is a discrepancy in what was previously incorrectly reported as the population coverage figures at the end of 2014-15 (11%) and what should have been reported (7%). The 8.7% figure being reported now, at the end of Q2, is a 1.7% increase and CPRD anticipates a further increase by the end of Q3, when data will begin flowing from the TPP GP software provider. However, the agency will not achieve the target of increasing population cover of primary care data within the CPRD system to 20% by financial year-end. This is therefore a red rating.

8.4   For PM8(b) with respect to FOI requests, Policy division has introduced a new process resulting in 99.7% of FOIs responded to within target. One FOI was not completed within the 20 working day target for Q2 but we expect to continue our high level of performance to date. Therefore, in line with previously accepted practice, this has been rated as 'green' because the high volume of FOI requests that we receive will enable the agency to increase performance to 99.9%, which would be rounded up to 100% at year-end.

8.5   The CET noted the progress against strategic activities and the additional measures that are being put in place to address those that are not currently on track.

9.   Information and Records Management: governance & addressing paper mountain (CET/15/258)

9.1   [redacted] and [redacted] presented an update to the CET on progress in creating the Information Asset Owner (IAO) role and supporting governance arrangements. An update was also provided on planning for the project to index and address the agency's extensive paper archive.

9.2   The CET noted that IAOs are now in place in all areas of business. It is the job of IAOs to provide assurance to the Senior Information Risk Officer that appropriate safeguards are in place in the business to manage information. The CET agreed the proposal for an Information Asset Board, chaired by the SIRO and comprising the appointed IAOs. This is a quarterly meeting, which will enable IAOs to fulfil their assurance responsibilities, receive guidance and consider new policies and processes for agency-wide implementation. The CET also agreed that the Information Asset Board should have oversight of the project to address the agency's paper archive. The CET supported the proposal to seek professional data handling expertise, whilst recognising that divisions and the appointed IAOs will have a significant role to play. The CET wanted to minimise any impact on existing divisional resources, particularly in VRMM and LD. It was agreed that any specific investments in resourcing to deal with the paper archive would need to be considered by the Information Government Board. The CET supported the proposal for a pilot project to better understand the amount of resources and expertise needed to effectively address the paper archive. Finally, the CET agreed that the Retention and Disposal Schedule would be agreed by the Information Asset Board.

10. Review of the Performance Management System 2015 (CET/15/259)

10.1   Vanessa Birchall-Scott and [redacted] presented a number of recommendations to improve the current Performance Management Scheme. The CET heard that the review – which was undertaken in September 2015 – had invited feedback from staff. Also considered in the review were the changes made to the DH performance management scheme.

10.2   The CET agreed all of the recommended improvements. Therefore, for the 2016/2017 performance year, the following changes will be made: (i) pre-validation ratings will be shared with staff, after the appraisal meeting (after agreement with the line manager and review within the Division/Centre); (ii) the 5 box rating system is retained but with updated descriptors; (iii) the three performance wave descriptors are amended; (iv) HR will undertake a complete overhaul of the documentation and support available on performance appraisal; and (v) a formal policy of monthly 1:1 meetings is implemented for all managers and their staff.

10.3   It was agreed that HR would develop internal communications to alert staff to the changes. In addition, the CET asked HR to look into the current process for handing appeals to determine whether any improvements can be made.

Action: (i) HR to develop internal communications to alert staff to the changes; (ii) HR to overhaul and update the current guidance and information; (iii) HR to conduct a review of the appeals process and report back to CET

11. HR Policy Development (CET/15/260)

11.1   [redacted] provided an update to CET on a project to map and review all existing HR policies. In addition, a new process for approving HR policies was presented for agreement. The CET noted the list of topics on which HR policy and guidance will be developed as well as the priority level attached to each one. Those considered to be of high priority will be developed first of all. The CET agreed that the proposed suite of policies was comprehensive and also agreed the prioritisation assessment. Finally, the CET agreed the process for developing, consulting on, and implementing any policy changes.

12. Investors in People (oral update)

12.1   Vanessa Birchall-Scott presented an oral update. The CET heard that the report of the agency's 'organisational health check' will be available on 13 November. It will then be sent to CET and any immediate actions will be progressed by HR in the coming weeks.

13. Quarterly report on division and centre bonus allocation (CET/15/261)

13.1   Vanessa Birchall-Scott presented the quarterly special bonus report for information. The CET noted this. It was agreed that the report would be reviewed again to confirm that all special bonuses awarded in the period specified had been captured; there was a feeling that some in IE&S may not have been included.

Action: HR and IE&S to confirm that all IE&S bonuses awarded in the given period had been included in the report

14. Managers' Conference action plan (CET/15/262)

14.1   [redacted] and [redacted] presented a proposal for responding to feedback given at the September Managers' Conference on how to improve employee engagement. The detailed feedback was provided in an annex, and this was noted by CET. The CET heard that all aspects of the feedback had been placed within 13 broad categories (e.g. pay and reward; networking; and shadowing and secondments). Each of these had been given a priority rating and a lead division responsible for taking forward any associated actions. This was agreed by the CET.

15. GOV.UK industry workshops (CET/15/263)

15.1   [redacted] updated the CET on work carried out in the last four months to develop the agency's presence on GOV.UK and to improve the customer experience of using the site. The CET noted the feedback from the workshops with industry, with a number of suggested improvements being taken forward by the Digital Communications team, including: creating a video to help users understand the email subscription service; clearer signposting for PILs, SPCs and PARs; adding content on risk management plans; and adding an organogram to the site. The CET recognised that the GOV.UK user experience remains far from ideal from an industry perspective, due to the fact that the website is aimed primarily at members of the public. Nevertheless, the Government Digital Service (GDS) – which has oversight of GOV.UK – has accepted that improvements to search and website navigation (particularly for specialist users) are a priority. Indeed a new team has been established at the GDS for this purpose. The CET heard that there have also been some significant successes that can be attributed to the transition to GOV.UK, such as a 20% increase in the readership of Drug Safety Update.

15.2   In conclusion the CET asked the Digital Communications team to continue to do all that is possible to improve the user experience for the agency's key stakeholders.

16. Digital Skills Review Update (CET/15/264)

16.1   [redacted] and [redacted] updated the CET on the progress of the digital skills review, which was agreed in July 2015 as part of the overall Annual Skills Review paper. The CET heard that the agency must provide information to the Cabinet Office on the level of skills available in the agency, not only in the area of digital skills, but also in the other three areas that are part of the Annual Skills Review (leading and

managing change; commercial skills and behaviours; and project delivery). The CET thought that a single data collection exercise should be carried out to avoid duplication. Discussions between the four leads would take place with a view to agreeing a light touch methodology for collecting information in order to generate a capability baseline for each area. This might involve adapting the draft survey produced by the digital skills team so that it covers all four areas.

17. Finance and Procurement Report (CET/15/265)

17.1   [redacted] resented the monthly Finance and Procurement report for the month of September and for the first half of 2015/2016. The CET noted the agency's total operating surplus for the year to 30 September £12.6m against a budgeted surplus of £8.3m. The operating surplus comprised £6.7m, £3.5m and £2.4m for the regulator, NIBSC and CPRD respectively. The cash position at 30 September stood at £222.1m and trade receivables were at £19.9m. The CET noted the significant expenditure variance on staff costs, which are now £2.6m (7%) below budget. The CET noted the Income Risk Assessment, the information on deferred revenue and the statement of financial position, including the detailed annex. Finally the CET noted the half yearly performance comparison.

INFORMATION

18. NIBSC SMT update (CET/15/266)

18.1   The CET noted the update from the NIBSC SMT.

19. NIBSC Management Review 21 July minutes (CET/15/267)

19.1   These minutes were noted. In relation to item (vii) on the Quality Management System, the CET noted that [redacted] was looking at the interface between the operating divisions (which are subject to the agency-wide ISO accreditation) and the corporate divisions (which are not).

20. CPRD SMT minutes (to 8 December meeting)

20.1   The latest minutes will be made available to the 8 December meeting.

21. Draft minutes of the 29 October Regulatory Group meeting (CET/15/268) and final minutes of 30 September Regulatory Group (CET/15/269)

21.1   The CET noted the draft minutes of the 29 October RG meeting and the final note of the 30 September meeting.

22. Updates from Cross-Agency teams

22.1   These were all noted by the CET.

Information Management Governance Board (7 Oct draft)	CET/15/270	Peter Commins
Finance Sub Committee meeting (17 Sept final)	CET/15/271	Peter Commins
SOP Working Group (5 Oct draft)	CET/15/272	Gerald Heddell
Health and Safety Working Group (next meeting 3 December)		Stephen Inglis
Audit and Risk Assurance Committee (June final)	CET/15/273	Peter Commins
Risk Management & Audit Liaison Group (next meeting 11 November)		Peter Commins

23. Agreement of 8 December CET agenda (CET/15/274)

23.1   The CET reviewed and agreed the agenda for the 8 December meeting subject to some minor alterations.

24. AOB

None.