Medicines & Healthcare products Regulatory Agency

Minutes (Final)

Title of meeting	Corporate Executive Team formal monthly meeting
Date	15 September 2015
Time	09.00 – 13.00
Venue	R-T-410, BPR
Chair	Ian Hudson
Attendees	CET
Apologies	Janet Valentine, Jonathan Mogford, June Raine, John Wilkinson

CET attendees:

Ian Hudson	Chief Executive (Chair)
Peter Commins	Chief Operating Officer and Director of Finance
Rachel Bosworth	Director of Communications
Stephen Inglis	Director of the National Institute for Biological Standards and 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
Valerie Field	deputising for Director of Devices
John Quinn	Director of Information Management division
Sarah Branch	deputising for Director of Vigilance and Risk Management of Medicines
Jon Ford	deputising for 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 June Raine, Director of Vigilance and Risk Management of Medicines; Janet Valentine, Director of Clinical Practice Research Datalink; Jonathan Mogford, Director of Policy; and John Wilkinson, Director of Devices. The Chief Executive welcomed [redacted] and [redacted] to the meeting as observers. 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 11 August Corporate Executive Team meeting (CET/15/201) including table of actions and final minutes of the 14 July Corporate Executive Team (CET/15/202)

2.1 The CET agreed the draft minutes of the 11 August CET meeting and noted the final minutes of the 14 July meeting.

STRATEGY

3. Corporate Plan refresh (CET/15/203)

3.1 [redacted] presented options for reviewing the agency's Corporate Strategy 2013-2018. The current strategy sets out a strategic framework for the agency and is used as a basis for developing the annual business plans. It outlines the key challenges and opportunities facing the agency over the 5 year period and sets out strategic objectives and areas of activity across five core themes.

3.2 At a number of recent meetings the CET has commented on the significant changes that are taking place in the areas covered by the Corporate Plan, including in the context of the strategic fees and cash discussions and the more recent discussions on the move to digital delivery of services as part of the information and technology strategy.

3.3 The CET considered options for the review, and agreed the need, in any type of review, to spend time scoping and defining the external environmental changes over the next 5 years, to help inform the response the agency needs to make. For the next stage the CET wanted to identify and explore in the agency's 8-10 top strategic issues. The selected areas would be those that have the potential to positively transform the way that the agency carries out its mission over the next 5 year period. A list was proposed in the paper and this was supported by the CET, with the addition of two others: excellence in customer services; and maintaining a world-class science base. It was also agreed to supplement the workforce topic with actions on pay and benefits. For each of the chosen topics the starting point would be 'what does success look like and what needs to be done to achieve it'. Enablers such as resourcing, and influencing and partnering with stakeholder organisations, would also be covered for each area.

3.4 The CET agreed the approach to the 23 September awayday to begin this process. The CET reiterated its intention to be ambitious, given the long time horizon and the pace of change in many of these areas. The CET agreed that early staff engagement and input would be a vital component of the review. It was agreed that the output of this work may require an addendum to the current Corporate Plan. Indeed there may be a need to reset the Corporate Plan timeframe so that a version covering the period 2016-2021 or 2017-2022 is published. A proposal will be made to the Agency Board in October outlining the proposed next steps.

Action: Policy to take the above comments on board and finalise the programme for the 23 September awayday

4. AAR: LD discussion paper on regulatory flexibilities and topics of interest in respect of methodology for generation of clinical evidence (CET/15/204)

4.1 [redacted] and [redacted] provided an update on the progress of George Freeman's Accelerated Access Review. The ARR is being led by the Office of Life Sciences with considerable input from across government. The AAR's stated aim is to 'speed up access to innovative drugs, devices and diagnostics for NHS patients'. Four workstreams have been established, as follows: (i) Articulating need, priorities and principles for innovation; (ii) Accelerated development pathways; (iii) Affordable national funding models to drive innovation; and (iv) Supporting affordable uptake and adoption. Each of these will be underpinned by user and patient engagement.

4.2 The agency has had a crucial role to play in influencing the direction of the review, through discussions with OLS and by contributing ideas and evidence. Input to date includes a full analysis of the areas that the agency wishes to see covered in the review, a list of innovative products and ideas drawn from the Horizon Scanning Group, proposals for EU reform, and a summary paper on clinical trial evidence generation.

4.3 The CET noted the current proposed outputs for each of the four themes with the most relevant aspects for the agency covered in workstreams (i) and (ii). The CET thought that the inter-agency 'Partnership Body' envisaged in workstream 1 needed very careful consideration. The aim is to provide a single source of advice for product development and a specification for data/evidence requirements across the pathway. The CET was concerned that any such body must not jeopardise the independence of the various agencies involved. It must also avoid adding unnecessary bureaucracy, or gold plating evidential requirements.

4.4 The CET commented on areas that might not currently be adequately covered, including the costs of clinical trials, translational medicine and using CPRD to enhance vigilance and surveillance. The agency will have an opportunity to comment on the final version of the proposed outputs in late September. The current timetable indicates that the final report will be available in April 2016.

5. Raising the awareness of dangers of counterfeit medicines and devices (CET/15/205)

5.1 [redacted] from Communications division presented an update on the development of a major public-facing communications campaign on the risks surrounding fake and illegal (FAIL) medicines and medical devices. The planned campaign will be long term – over a 2-3 year period – and will aim to build on and complement the excellent work to date to raise awareness of these dangers. It was noted that the ongoing work to highlight successful prosecutions and working with media to highlight the results of Operation Pangea will continue. Likewise the work to publicise the Falsified Medicines Directive logo requirements will continue (the public campaign is planned for December or January and a plan will be submitted to the Regulatory Group for approval in November).

5.2 The CET heard that the nature of the long-term campaign and the specific activities and areas of focus will be informed by the extensive desk research which is already well underway. The CET heard that the research has identified the types of products that are most susceptible to fake or illegal manufacture and purchase by the public, and the demographic profile of the types of people that are most likely to purchase products online (the single largest source of fake and illegal products). The next stage is to identify potential partnerships that the agency can use to enhance the impact of the campaign, working across government, with industry or indeed with other stakeholder organisations. Learning from other organisations (including the Food Standards Agency) is also part of the research. The extensive desk research will ensure that the resources appointed to the project can be targeted for maximum impact. The CET agreed to review the research findings and the analysis report and recommendations for the campaign strategy at its December meeting. The campaign will start early in 2016.

Action: Communications division to: (i) continue working on the campaign and bring a paper back to the December CET meeting; (ii) submit a proposal for the public facing FMD logo campaign to the November RG

6. Moving towards greater transparency around animal work (CET/15/206)

[Section 35 redaction: formulation of government policy]

GOVERNANCE & DELIVERY

7. Triennial Review: progress against recommendations (CET/15/207)

7.1 [redacted] returned to CET to seek agreement to a register outlining the progress in implementing the recommendations of the triennial reviews into the agency as a whole, the Commission on Human Medicines and the British Pharmacopeia Commission. The CET agreed that good progress had been made in taking forward the recommendations, with some already having been completed. The CET identified a number of areas that needed to be updated and directors agreed to provide comments to Policy division as

a matter of urgency so that a revised version can be made available to the Agency Board in advance of the 18 September meeting.

Action: (i) directors to provide comments to Policy in the areas discussed; and (ii) Policy to update the register for the AB meeting

8. E-cigarettes: fees proposals (CET/15/208)

[Section 35 redaction: formulation of government policy]

9. IT strategy update (CET/15/209)

9.1 John Quinn presented an update on the agency's IT strategy and summarised the status of the main priority areas. The CET discussions focused on the extent of the agency's ambition in terms of 'going digital'. The CET agreed that the agency needed to keep pace with developments in the digital domain. Simply updating or replacing current applications with 'like for like' would be very costly. Only by conducting a root and branch review of the processes that underpin the digital services will the agency accrue the significant cash and non-cash benefits available and so minimise overall net costs. The CET agreed that the move away from a single infrastructure provider [redacted – Section 43 Commercial Interests] had provided an ideal springboard to consider how the organisation can make full use of digital approaches to transform how we operate – particularly in terms of meeting the needs and expectations of customers.

10. Performance Management: mid-year scheme/process review (CET/15/210)

10.1 Vanessa Birchall-Scott presented an update on the review of the Performance Management annual process. At its meeting in January 2015 the CET had considered a review of the 2013/2014 performance management year and had agreed to adopt some minor changes for 2014/2015. At that time it was agreed to review the process once more, following the completion of the 2014/2015 appraisal round. The CET heard that this review commenced in July 2015. Comments and reflections on the 2014/2015 process had been invited from divisional representatives of the Performance Management Group and from union representatives on the Industrial Relations Liaison Committee. A general invitation to comment would be put out in INsite shortly.

10.2 The CET also heard that the Department of Health had introduced significant changes to its process for the 2015/2016 round, with a move away from the 'what' and 'how' five box approach to a model with much less opportunity for differentiation. Some changes to moderation, validation and the appeals process have also been made in DH and these in effect align DH with changes already made by the agency. The DH changes to a three box model and performance wave will be considered as part of the agency's review. The CET's strong preference was to avoid unnecessary tinkering and to alter the process only when the benefits of doing so are clear. The CET stated that there will be no changes mid-year.

Action: HR to continue the Performance Management review and submit the results and any recommendations to the November CET

11. Customer services internal campaign (CET/15/211)

11.1 [redacted] presented a proposal for an internal engagement campaign with staff to seek views on how the agency can become more customer focussed. Excellence in customer services is a key part of the Communications and Reputation Strategy, which the CET approved in September 2014. It is implicit in a number of the key areas of focus in the strategy. The CET noted that various sources of intelligence are available to give an indication of how the agency's customer services are perceived, including: the annual perceptions audit managed by the Patient, Public and Stakeholder Engagement team in Communications division; the annual satisfaction survey targeting people who contact the Customer Services Team; the recent customer insight research with Licensing division and the British Pharmacopeia; the recent Triennial

Review of the agency; and discussions with, for example, trade associations (including the BGMA annual survey). The CET agreed to limit this work – at least initially – to external customers. The proposal was agreed by CET and further details will be made available to staff in due course, including on how to provide views and input.

12. Finance and Procurement Report (CET/15/212)

12.1 [redacted] presented the monthly Finance and Procurement report for the month of July and for the four months of financial year 2015/2016. The CET noted the agency's total operating surplus for the year to 31 July of £10.0m against a budgeted surplus of £5.2m. The operating surplus comprised £5.4m, £3.6m and £1.1m for the regulator, NIBSC and CPRD respectively. The cash position at 31 July stood at £214.7m and trade receivables were at £29.2m

12.2 The main component of the agency's above budget performance remains DCP RMS, which is £1.0m above budget, and NIBSC income from flu standards, which is £1.3m above budget. The CET noted the Statement of Financial Position (SFP) and the analysis and illustration of debtors, receipts and payments on account.

INFORMATION

13. NIBSC SMT Report (CET/15/213)

13.1 Stephen Inglis presented the NIBSC SMT report ad highlighted the recent discussions on investment planning. This was noted by the CET. It was agreed that the NIBSC SMT minutes will be made available to future CET meetings, which is in line with the inputs from CPRD and the regulator.

14. CPRD SMT Report (CET/15/214)

14.1 The CET noted the minutes of the CPRD Executive Committee meeting of 9 July.

15. Draft minutes of the 1 September Regulatory Group meeting (CET/15/215) and final minutes of 28 July Regulatory Group (CET/15/216)

15.1 These were noted by the CET.

16. Update on MHRA Investors in People Continuous Improvement Revalidation Plan 2015 (CET/15/223)

16.1 Vanessa Birchall-Scott presented this update. The CET heard that there have been some delays in securing an assessor to conduct the IIP Health Check. When this is complete the CET will take a view on next steps, including on whether to apply for reaccreditation or to consider alternative organisational development opportunities.

17. Updates from Cross-Agency teams

17.1 These were noted.

Information Management Governance Board (2 Sept. draft)	CET/15/217	Peter Commins
Information Management Governance Board (1 July final)	CET/15/218	Peter Commins
Finance Sub Committee meeting (16 July final)	CET/15/219	Peter Commins
SOP Working Group (next meeting 7 Sept)		Gerald Heddell
Health and Safety (June final)	CET/15/220	Stephen Inglis
Audit and Risk Assurance Committee (next meeting 16 October)		Peter Commins
Risk Management & Audit Liaison Group (May final)	CET/15/221	Peter Commins

18. Agreement of 13 October CET agenda (CET/15/222)

18.1 This was agreed.

19. AOB