Medicines & Healthcare products Regulatory Agency

Minutes (FINAL)

Title of meeting	Corporate Executive Team (formal) monthly meeting
Date	10 March 2016
Time	09.00 – 13.00
Venue	501, BPR
Chair	Peter Commins
Attendees	CET
Apologies	Ian Hudson, Rachel Bosworth Jonathan Mogford

Peter Commins	Chief Operating Officer and Director of Finance (Chair)
Stephen Inglis	Director of National Institute for Biological Standards & Control
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
June Raine	Director of Vigilance and Risk Management of Medicines – for items 1-5
Sarah Branch	deputising for the Director of VRMM for items 6-24
Janet Valentine	Director of the Clinical Practice Research Datalink
Mark Wilson	DH Legal Services

Additional attendees

[Names redacted under section 40 of the FOIA (personal data)]
Richard Humphreys, Finance and Procurement, for item 14: review of agency's external fraud register

1. Apologies and Announcements

1.1 Apologies were received from Ian Hudson, Rachel Bosworth and Jonathan Mogford.

1.2 [Name redacted under section 40 of the FOIA (personal data)]

2. Draft minutes of the 2 February Corporate Executive Team meeting (CET/16/054) including table of actions and final minutes of the 5 January Corporate Executive Team (CET/16/055)

2.1 The CET agreed the draft minutes of the 2 February CET meeting and noted the final minutes of the 5 January meeting.

3. Draft minutes of the Board meeting of 12 February (CET/16/056); final note of the Board/CET away day of 15 January (CET/16/056) and final minutes of the Board meeting of 9 December (CET/16/58)

3.1 The CET noted the draft minutes of the 12 February Board meeting, the final version of the note of the Board/CET away day of 15 January, and the final minutes of the 9 December meeting.

STRATEGY

4. Corporate Plan review and Business Plan 2016/2017 (CET/16/059)

4.1 [Name redacted under section 40 of the FOIA (personal data)] presented a revised update to the Corporate Plan 2013-18, along with the draft Business Plan for 2016-17, both of which would go to the Board in time for its meeting on 14 March. The CET endorsed the draft Corporate Plan update, which it was agreed could go to the Board for its meeting on 14 March.

4.2 As regards the draft Business Plan, [Name redacted under section 40 of the FOIA (personal data)] explained ongoing discussions with the Department of Health about the final targets for increasing Clinical Practice Research DataLink (CPRD) coverage during 2016-17; and that there may be subsequent amendments on this section alone. The CET asked that clarification be sought quickly from DH about the target; meanwhile, the CET asked that the Board should receive a draft copy of the Business Plan, with the caveat that discussion of the CPRD business target was still taking place with DH. The CET asked that the Board be advised of the outcome of these discussions at its meeting on 14 March.

4.3 Meanwhile, a revised cover note for the Board meeting would be prepared. The CET also commended colleagues in Policy Division for their work on the Corporate Plan update and draft Business Plan.

5. Budget (CET/16/060)

5.1 Peter Commins introduced [Name redacted under section 40 of the FOIA (personal data)], who presented the draft budget for 2016/17. The paper included an update to the strategic financial position outlined in the report to the CET and Board in January 2016 and set out the position for the 2017/18 Regulator fees' round. Additionally, the Budget paper outlined the budgetary position for the Regulator, the NIBSC, and CPRD, and included a section on DH funding.

5.2 [Name redacted under section 40 of the FOIA (personal data)] reported that 2016/17 was year four of the current five year financial objective period and adherence to the recommended budget would mean the agency will exceed its current required rate of return by approximately £60m (130%) by 2018. Over the remainder of the current 5 year financial objective period the regulator would make a small surplus in 2016/17 before going into deficit in 2017/18 where it would remain throughout the next five year period unless it offsets the costs of IT investment and the predicted decline in income. The increase in agency pay costs in the budgets is consistent with short term operational delivery being the priority for the regulator, and the growth plans in NIBSC and CPRD. The regulator's pay costs will increase due to over-recruit into hard to fill posts in order to offset turnover, the deliberate encouragement of fixed term post investments given the current capacity to afford these activities and the deliberate pausing of the existing manpower savings' plans (125 posts over three years) whilst short term income permits.

5.3 The CET agreed that there needed to be CET ownership and visibility of the future manpower plans. There was a discussion as to whether fee-earning posts should be excluded from any future reduction in posts. It was thought this in isolation would be potentially divisive, as it implied that non-fee earning posts were the only ones which could benefit from being more efficient or were not as important, and would be inconsistent with the accepted position that fees were an imperfect measure of the regulator's activities. The CET agreed that the approach to the Agency's headcount required strategic discussion, as it touched on wider areas of work. The CET agreed that staff would need to be informed regularly about progress to date with the headcount reduction and agreed that there was time for a concerted preparation of plans during 2016/17 rather than a need for panic measures.

CET agreed the priority to identify a plan to establish the regulator's sustainable medium term position and recommended that the CEO as accounting officer approves the 2016/17 budgets.

6. British Pharmacopoeia Business Review (CET/16/061)

6.1 [Name redacted under section 40 of the FOIA (personal data)] outlined a business review of the British Pharmacopeia's operations and product portfolio that was carried out in response to the recommendations made by the Triennial Review team. The Business Review also took into account feedback received from the Insight Research Project from 2015. [Name redacted under section 40 of the FOIA (personal data)] explained that the proposals set out in the paper represent a radical shift from the current business model.

6.2 The CET considered the a number of recommendations set out in the Business Review, namely: to bring the digital element in-house and differentiate the product portfolio by the introduction of a "Sky package"; reduce and simplify the cost to industry (by reducing and standardising the cost of the BP's Chemical Reference Substances) and move closer to cost recovery, rather than over-recovery, improve customer service by implementing process improvements; and finally assess and manage the capability and capacity gaps (incl. staff, skills knowledge and laboratory). The future location of the laboratory function was also discussed as the contract with LGC is due to end in 2021. It was agreed that an assessment was necessary to determine the possible future options for this function.

6.3 The CET welcomed the paper and commented on a number of aspects of the report. Concerning the proposed abolition of freight charges, which account for approximately 4% of income, it was noted that freight charges for biological products can be much more expensive that for other products. It was agreed that freight charges would remain for resellers and that there would be a charge for samples with special delivery and transportation requirements (such as controlled substances) and that biologicals could be considered in this context. It was noted that the move towards cost recovery was in accordance to the recent Triennial Review's recommendations, in line with other cost cutting activities (e.g. reduction in fees) and would be a good response to the feedback received suggesting that the BP products and services are expensive.

6.4 The CET supported the direction set out in the paper, in particular, the recommendation to upskill to enable the digital element to be brought in house as CET suggested that these new skills could be further utilised across the Agency and not just for the BP. A feasibility study will be undertaken to integrate the digital element with tailored product package over the next few years and regular updates will be provided to CET to ensure continued agreement with the direction of travel. The price adjustments were agreed and will be implemented in August, in line with the next edition of the BP.

7. Implant registries (CET/16/062)

7.1 [Name redacted under section 40 of the FOIA (personal data)] presented an update on implant registries and, in particular, progress on: (i) MHRA working with UK implant registries; and (ii) the development of international guidance on implant registries.

7.2 The CET heard that implant registries are a key element of MHRA's work on the safety of implantable medical devices. [Name redacted under section 40 of the FOIA (personal data)] reported that MHRA is working with UK implant registries to improve their capability to support the Agency's post-market surveillance activities and has participated in the development of international guidance on implant registries. The update covered the Agency's work with UK registries including the Breast Implant Registry and the National Institute for Cardiovascular Outcomes Research (NICOR), as well as international work with the International Medical Devices Regulatory Forum (IMDRF) and on other registry collaborations such as the International Collaboration of Breast Registry Activities (ICOBRA) and ***Devices without Borders*** (cardiovascular implant registries).

7.3 The CET noted the summary of planned work for 2016, which is to:

- Continue to work with UK implant registries to further improve their contribution to device post-market surveillance.

- Work with Health and Social Care Information Centre (HSCIC) on the development of the National Breast Implant Registry, in support of Keogh Recommendation 21.

- Work with NICOR on the further development of UK cardiovascular registries and consider their proposal to hold a joint workshop for cardiovascular device manufacturers.

- Continue to contribute to IMDRF work on the development of international guidance on implant registries.

- Contribute to the ***Devices without Borders*** collaboration on cardiovascular implant registries.

7.4 The CET asked for an update in March 2017 on registries and linked activities on UDIs and pooled European vigilance data.

Action: Devices Division to provide an update in March 2017.

8. Growth Strategy (CET/16/063)

8.1 [Name redacted under section 40 of the FOIA (personal data)] gave an update on recent work on the Growth agenda. The update outlined six areas of upcoming work: (i) training, (ii) NIBSC, (iii) IT, (iv) UK investment, (v) UK science, and (vi) genomics and companion diagnostics. The CET noted that the British Pharmacopoeia's role in the Growth agenda had been addressed under a separate paper earlier in the meeting. [Name redacted under section 40 of the FOIA (personal data)] went on to report that Dr Hudson, Chief Executive, would discuss this in more detail with relevant Directors, notably the ones involving substantial possible expenditure, before fuller or formal commitments are made. Consideration is also being given to how delivery of this activity could best be pursued. The CET welcomed the update and supported the approach set out in the paper.

9. Events Strategy (CET/16/064)

9.1 [Name redacted under section 40 of the FOIA (personal data)] presented a paper that outlined the findings of a review of the Agency's approach to events' planning, along with a set of recommendations for next steps. [Name redacted under section 40 of the FOIA (personal data)] provided an overview of the Agency's events' programme, which has grown significantly over the past three years, and which has generated around £1million in income during the current financial year. [Name redacted under section 40 of the FOIA (personal data)] then set out the findings from the recent review. These covered: (i) activity, spend and income; (ii) evaluation and outcomes, (iii) brand positing, and (iv) strategic planning.

9.2 The CET stated that on principle the Agency's events' programme has to have a public health purpose and the approach to cost should be flexible. Flu vaccine work was cited as an example of where an important income-earning area for the Agency requires a degree of subsidy in order for key stakeholders from academia to attend Agency-organised workshops and conferences. Without that academic input, the Agency's ability to carry out vital work would be severely inhibited. The CET also agreed that it was important that a more strategic and thoroughly joined-up approach be adopted towards events' work. It was agreed that early engagement with the events' team was vital, with all concerned doing their best to exploit fully the opportunities presented by Agency events. The CET endorsed the report and its direction of travel.

GOVERNANCE & DELIVERY

10. Developing our people: progress report on career pathways work – planning and implementation (CET/16/065)

10.1 [Name redacted under section 40 of the FOIA (personal data)] presented a progress report on the career pathways project. The report covered phase 1 (the development of a competency knowledge and skills' framework) and Phase 2: work to map these on to a development plan.

10.2 [Name redacted under section 40 of the FOIA (personal data)] explained that the People Strategy recognised that the Agency needed to take specific steps to attract and retain competent staff, whilst developing more flexible workforce. Phase 1 of the career pathways work is to develop skills and knowledge framework for each Division, identifying core, technical and other skills for roles within specific grades. The CET heard that Devices Division has produced its own framework, and other Divisions in the cross agency working group agreed to use the same format as Devices so as to produce a standard approach. The CET noted that Phase 1 should be completed by end March 2016; Phase 2 will then map the skills to a clear sequence of learning and development. This work is already underway in Devices.

10.3 The CET welcomed the report and agreed that a dedicated fixed-term staff resource be allocated to coordinate this work. The CET noted that the secondment opportunity will be for one year at Grade 7 or Senior Executive Officer level. A number of CET directors advised that staff should be encouraged to see the benefits of sideways movement with the organisation, as a way of developing and cross-fertilising the Agency's pool of knowledge and skills.

The CET thanked [Name redacted under section 40 of the FOIA (personal data)] for her report and commended the members of the cross-agency group, in particular, [Name redacted under section 40 of the FOIA (personal data)].

Action: Human Resources Division to proceed with recruiting a secondee for one year for the career pathways project.

11. Civil Service People Survey: agency action plan approval (CET/16/066)

11.1 Vanessa Birchall-Scott referred to the draft agency-wide and divisional People Survey action plans. These had been developed following responses from members of staff to the People Survey of October 2015. The CET noted that action plans sought to build upon the 2015 action plans, as well as respond to the key messages that have been fed back from the recent staff survey. Vanessa Birchall-Scott made specific reference to a number of the items in the agency-wide plan and noted that these needed to be discussed further in divisional SMTs as managers had a role in progressing.

11.2 The CET endorsed the draft agency-wide action plan, as well as the divisional action plans. Vanessa Birchall-Scott asked for any final comments to be sent on by 11 March, after which all plans would be published on Insite. A further paper would come to the CET in July 2016.

12. Clinical trials activity (CET/16/067)

12.1 Dr Siu Ping Lam briefly introduced [Name redacted under section 40 of the FOIA (personal data)], who presented a report on clinical trial activity, which covered: (i) the number of clinical trial applications for medicines that have been received by the Agency's Clinical Trials Unit (CTU), (ii) the CTU assessment performance, and (iii) the Agency's position in Europe, including initiatives to streamline approvals of multi-member state trials.

12.2 The CET noted that applications for clinical trial authorisations (CTAs) in the UK continue to increase with an 11% increase in total CTA applications in 2015 compared with the previous year. Moreover, the numbers of both commercial and non-commercial studies have increased in recent years. The CET noted that the historical decrease in Phase 1 studies had stabilised in recent years and in 2015 increased by 9% compared with 2014.

12.3 [Name redacted under section 40 of the FOIA (personal data)] reported that the UK (MHRA) maintains a leading position in Europe as a preferred place to conduct clinical trials of medicines. Additionally, the Agency is taking a leading role in harmonising clinical trial assessment throughout Europe by acting as a reference competent authority for the majority of procedures submitted under the Voluntary Harmonisation Procedure (VHP).

12.4 The CET commended [Name redacted under section 40 of the FOIA (personal data)] and colleagues in the CTU on their success, and recommended that the report of the CTU's work be given more publicity. [Name redacted under section 40 of the FOIA (personal data)] mentioned that he had given a report of the CTU's work to the ABPI MISG Clinical Research Working Group in January 2016. It was also suggested that the report be published on GOV.UK and should be presented to the UK Clinical Research Council.

13. Digital strategy quarterly report - (CET/16/068) – deferred to the April 2016 CET meeting

14. GOV.UK – the first year (CET/16/069)

14.1 [Name redacted under section 40 of the FOIA (personal data)] gave a progress report on the Agency's presence on the GOV.UK website, one year on from the transition from the Agency's independent website. The CET heard that the full transition of the MHRA website to GOV.UK had been completed at the end of January 2015. This represented a major change to the way the Agency's stakeholders interact with our corporate and regulatory digital content.

13.2 The CET was advised that good progress has been made during the agency's first year on GOV.UK and a number of areas of feedback, particularly from medicines and devices industry users, have been addressed. The report also outlined the key achievements over the past year, such as the Inspectorate blog, the GOV.UK user workshops, the all services and information page, and publishing process. In the latter case, there have been 600 content updates over the past year.

13.3 The CET welcomed the report but thought that more work needed to be done to continue to address stakeholders' concerns.

15. Review of the Agency's External Fraud Register (CET/16/070)

15.1 Richard Humphreys presented the External Fraud Risk Register, which was last reviewed by the CET and the Audit and Risk Assurance Committee in October 2016. The CET noted that the register was now in a new 5x5 risk matrix format, which allows the Agency to quantify the severity of external fraud risks. The CET heard that a common theme that runs through potential external fraud risks is the use of falsified data by external organisations and / or individuals for fraudulent purposes. Mr Humphreys advised there were no significant changes or new risks to report.

16. Reported cases of Regulatory Fraud (CET/16/071)

16.1 Richard Humphreys presented a report on the number of reported incidents of regulatory fraud in the Agency from April 2015- February 2016. The CET heard that this was the first time that such a report was being compiled for the CET, which would go to the Audit and Risk Assurance Committee in time for its meeting on 14 March. The report covered incidents that were reported by the following divisions: Licensing, Devices, and Inspection, Enforcement and Standards. Two other divisions (NIBSC and Vigilance and Risk Management of Medicines) submitted nil returns. The CET welcomed the report, which was noted.

17. Agency Assurance Mapping (CET/16/072)

17.1 Richard Humphreys presented a paper on the Agency's approach to Assurance Mapping. The CET heard that assurance mapping is one of the sources of assurance that the Accounting Officer (AO) draws upon in providing the AO's overall assurance in the Governance Statement.

17.2 The CET reviewed the Assurance Mapping document, which, it thought was a very useful tool. Dr Inglis reported that NIBSC has considerable experience of assurance mapping, which predates its merger with the Health Protection Agency; that assurance mapping is now firmly embedded in NIBSC's culture and practice of work. The CET heard that NIBSC's experience of assurance mapping was positive, and was one which the NIBSC would share with colleagues across the Agency.

17.3 While reviewing the assurance mapping document, the CET queried the large amount of grey areas, which indicated that more work was required to improve the document. As part of this process, CET asked

that further work be done to identify where there may be gaps, especially in training. Dr Inglis said that [Name redacted under section 40 of the FOIA (personal data)] would share with colleagues' NIBSC's experience of using assurance mapping.

17.4 As to sustainability, Dr Inglis reported that NIBSC's sustainability manager has been nominated for two national categories.

Action: NIBSC to share its experience of assurance mapping with other divisions.

18. Finance and Procurement Report (CET/16/073)

18.1 Richard Humphreys presented the monthly Finance and Procurement report for the month of January and for the first ten months of the 2015/2016 financial year. The CET noted the agency's total operating surplus for the year to 31 January of £20.5m against a budgeted surplus of £13.08m. The operating surplus comprised £12.8m, £5.5m and £2.2m for the regulator, NIBSC and CPRD respectively. The cash position at 31 January stood at £218.3m.

18.2 The CET noted that the operating income for the Agency was £132.3m, which is £5.8m (5%) above budget. Total operating costs were at £111.7m, which is £1.7m below budget. The number of full-time equivalent staff in post in January 2016 was: 1,246, with 155 staff on short-term contracts and 45 non-payroll employees. Capital expenditure at the end of January was £7.2m, whole the total product licensing deferred revenue at the end of January was £18.3m.

18.3 The CET considered appendix 6 to the report (issues identified by the NAO at the interim audit. This concerned Cabinet Office Controls that must be observed over certain areas of expenditure. Richard Humphreys reported that the Agency has robust processes in place for most areas covered by the controls, but that a flexible approach to its operation was needed to ensure that the Agency met its obligations to adhere to the Cabinet Office Controls. The CET stated that such flexibility is possible so long as the required business case and permissions (from line management) are in place.

19. Corporate Risk Register (CET/16/074)

19.1 Richard Humphreys presented the agency's Corporate Risk Register (CRR), which was last seen by CET and by the Audit and Risk Assurance Committee (ARAC) in January. ARAC will review the CRR again on 14 March.

19.2 The CET welcomed the opportunity to review the CRR and it agreed there was scope to reduce the number of risks on the register. Accordingly, the CET decided that risks 1, 13, 24 and 25 should be removed. It was agreed that risk 1 was already covered by risk 6, while risks 24 and 25 have been on the CRR since 2008 and the case for keeping them on was no longer valid. This reduced the number of the risks on the CRR from 25 to 21. No new risks were added to the CRR.

19.3 The CET had a wider discussion about risk-taking, and agreed that there were 'good risks' that were worth taking, which is something the CET would wish to consider at a later date. The CET also noted the risk associated with flu standards' income.

Action: The following risks to be removed from the CRR: 1, 13, 24 and 25.

INFORMATION

20. NIBSC SMT update (CET/16/075)

20.1 The CET noted the update from the NIBSC SMT.

21. Draft minutes of the 23 February 2016 Regulatory Group meeting (CET/16/076) and final minutes of the 19 January 2016 Regulatory Group (CET/16/077)

21.1 The CET noted the draft minutes of the 23 February RG meeting and the final note of the 19 January meeting.

22. Updates from Cross-Agency teams

22.1 These were all noted by the CET.

Information Management Governance Board (CET/16/078)
Information Management Governance Board (CET/15/079)
Finance Sub Committee meeting (CET/16/080)
SOP Working Group (CET/16/081)
Health and Safety Working Group (16/082)
Audit and Risk Assurance Committee (16/083)
Risk Management & Audit Liaison Group (CET/16/084)
Risk Management & Audit Liaison Group (CET/16/085)

23. Agreement of 5 April CET agenda (CET/16/086)

23.1 The CET reviewed and agreed the agenda for the 5 April meeting, subject to a number of changes. They were: HR to add a paper on pay for the April CET, while the paper on Reputation Risk index would be deferred to May.

24. AOB

24.1 John Quinn updated the CET on IT network availability over the coming weekend.