



# Medicines & Healthcare products Regulatory Agency

## Minutes (Final)

<b>Title of meeting</b>	Corporate Executive Team formal monthly meeting
<b>Date</b>	14 July 2015
<b>Time</b>	09.00 – 13.30
<b>Venue</b>	R-T-410, BPR
<b>Chair</b>	Ian Hudson
<b>Attendees</b>	CET and additional attendees (see below)
<b>Apologies</b>	John Quinn

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
Jonathan Mogford	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
Alexis Castillo-Soto	Deputising for the Director of Information Management division
June Raine	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 John Quinn, Director of IMD. 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 remain confidential.

### 2. Draft minutes of the 19 June Corporate Executive Team meeting including table of actions (CET/15/154) and final minutes of the 12 May Corporate Executive Team (CET/15/155)

2.1 The draft minutes of the 19 June CET meeting were agreed. The CET reviewed the table of actions and an updated version was subsequently sent to CET. The final minutes of the 12 May CET meeting were noted.

### **3. Draft minutes of the Agency Board meeting of 22 June (CET/15/156) and final minutes of the Agency Board meeting of 15 May (CET/15/157)**

3.1 The CET heard that the draft minutes of the Agency Board meeting of 22 June 2015 were still being prepared, while the final minutes of the 15 May 2015 meeting were noted by the CET.

## **STRATEGY**

### **4. Academic and research priority stakeholders (CET/15/158)**

4.1 Stephen Inglis presented a paper on the opportunities for the Agency to build strategic relationships with the life sciences academic community. The paper followed a discussion by the CET and Board earlier in the year where there was broad agreement that the development of such relationships and the maximising of synergies between the Agency and the academic life sciences sector were very important.

4.2 Stephen Inglis outlined the benefits to the Agency and its academic partners of having such a strategy in place. For example, such a strategy would broaden the Agency's expertise and knowledge, strengthen horizon scanning and would maintain a culture of evidence based decision making. While for the academic partners, it would offer funding opportunities from collaborative work and allow access to specialist materials and facilities.

4.3 The CET endorsed strongly the importance of having such a strategy, which could support business and would chime with the Agency's corporate and business plans. During the discussion, it was suggested that work on vaccines for new/emerging public health threats could be broadened out to cover therapeutics as well; vaccines for emerging public health threats is a priority for the Prime Minister. Other priorities included real world data and its use for vigilance (both medicines and devices), regenerative medicines and clinical trial design. In the discussion the CET noted that whilst the focus was on academic relationships, this was not to the exclusion of other organisations that may have a role to play.

4.4 The CET asked Stephen Inglis to develop a comprehensive plan that would set objectives, methodology (who we should be talking to), the optimal approach so as to draw in potential academic partners, and an action plan with timelines. Stephen Inglis thanked the CET for its comments, which would help inform the discussion on the same subject at the Board on 20 July. An update will return to the CET in October 2015.

**Action:** Stephen Inglis to take forward work on the draft Strategy and action plan.

### **5. Next Generation Sequencing (CET/15/159)**

5.1 [redacted] of Devices presented a paper on the regulation of Next Generation Sequencing (NGS), which is a ground-breaking technology that is now being used in many areas of healthcare. They include clinical genetics, microbiology, oncology, fertility care, drug prescribing, and drug development. Mr Lee went on to outline the clinical applications of NGS, NGS technologies in 'wet' and 'dry' laboratories, NGS and stratified medicines, and the use of NGS within clinical laboratories. Mr Lee concluded by updating the CET on the Agency Open Day on the Regulation of NGS, which was held on 3 July 2015. The Open Day included speakers from the Royal College of Pathology and an open forum discussion that was facilitated by Vivienne Parry of Genomics England.

5.2 The CET welcomed the paper, including the update on the success of the recent open day. Then CET thought that developing our response to NGS was very important for the Agency. The CET asked that a detailed plan of action be brought to the CET by October for the CET to review and consider progress.

**Action:** (i) Devices to prepare a draft Action Plan on NGS for the September or October CET meeting

## GOVERNANCE & DELIVERY

### 6. Quality Management System – management review (CET/15/160)

6.1 [redacted] and [redacted] presented a paper on the annual management review of the Quality Management System. The annual management review is required in order that the Agency can retain its certification to ISO 9001. [redacted] gave an overview of the Agency's certification, which dates back to 1994, and explained that the management review covered the internal and external audits, the pharmacovigilance audit, the outcome of two complaints investigations, as well as the resources to maintain the QMS. [redacted] report also covered customer feedback, performance measures, controls of non-conformity, changes affecting the QMS and opportunities for improvement.

6.2 [redacted], who will succeed [redacted] as the Agency's lead on QMS after [redacted] retirement at the end of July 2015, explained the new approach to QMS: with quality coordinators embedded in each of the Agency's Centres. There will separate QM systems for NIBSC and MHRA but they will be linked through a common manual. [redacted] also reported that the new IE&S quality manager will join the Agency on 20 July. Meanwhile, [redacted] will work with the Quality Coordinators to identify any gaps and training requirements. This will help bed in the new structure and identify any resource issues or other risks that could help identify the Agency's certification status.

6.3 The CET welcomed the update and endorsed the approach set out in the paper. The CET queried whether the Audit and Risk Assurance Committee should receive an update on QMS and asked the COO to consider. The CET asked for a further update after six months.

6.4 In conclusion, Dr Hudson asked that the minutes record the CET's gratitude to [redacted] for his work on QMS over the past twenty years and their best wishes as he prepares for retirement.

**Action:** (i) QMS leads and coordinators to consider a possible renaming of the SOP Working Group  
(ii) the CET to receive a further update in January 2016

### 7. Customer insight research findings (Licensing and BP) (CET/15/161)

7.1 [redacted] of Communications Division and [redacted] of IE&S presented the key findings from customer insight research on Licensing Division and the British Pharmacopoeia (BP). When the Agency agreed its first marketing plan in September 2014, that plan included a commitment to carry out detailed customer insight research in two areas. The research would help gain a deeper understanding of the Agency's customers and their needs. Licensing and the BP were the first areas to be selected.

7.2 The CET heard that the Licensing Division research showed MHRA to have a strong reputation and high satisfaction ratings for the DCP process. However, the research also identified areas that could be improved. As for the BP, the CET heard that it is highly valued and has a strong reputation and is considered to be one of the top three pharmacopoeias in the world. Again, the research revealed areas that could be improved.

7.3 The CET asked about the cost drivers, the future of the BP, especially in relation to the European Pharmacopoeia, and what was being done to address the areas for improvement highlighted in the two reports. The CET heard that short term, task and finish cross-agency working groups will be set up to address the points in the LD report. In regard to the BP, the CET heard that the BP's position will continue to be strong; moreover, the planned actions to address the points in the report will enhance the BP's strong position. Furthermore, work has started on the development of a

marketing and communication strategy, which will be ready for the CET to consider in six months' time (February 2016).

**Action:** (i) A BP marketing and communication strategy, which will highlight the work being carried out in response to the research findings, to come to the CET in February 2016; (ii) Cross-agency working groups, addressing the issues highlighted by the Licensing research, to report progress to CET /Regulatory Group in December 2015

## **8. September 2015 Managers' Conference (CET/15/162)**

8.1 [redacted] presented a paper on the design and content of the managers' conference on 11 September 2015. The paper also included a review of feedback from the Senior Leaders Group meeting on 9 June 2015. The CET endorsed the proposed programme, which they thought was excellent, including the use of David MacLeod of Engage for Success as the key note speaker. Mr MacLeod's section will focus on how employee engagement improves organisation performance. The CET thought it would helpful if delegates had some relevant pre-conference reading material.

8.2 The CET considered the relatively low attendance rate among some managers at recent managers' conferences. It was agreed that it would be best if directors addressed this matter within their own divisions, using the list provided with the paper. The message that needs to be communicated was that there was a high expectation that, wherever possible, managers should attend the half-yearly managers' conference. It was agreed that if managers cannot attend, they should make their divisional director aware of their decision and the reasons for non-attendance.

## **9. Annual skills capability planning (CET/15/163)**

9.1 Vanessa Birchall-Scott updated the CET on progress since the CET's discussion of the Annual Skills Survey and capability planning in January 2015. The CET noted the progress achieved to date and endorsed the action plans for four specific areas: leading and managing change, project delivery, digital skills, commercial skills and behaviours. It was agreed to review progress again in January 2016.

## **10. People Survey Plans and 2014 People Survey update (CET/15/164)**

10.1. Vanessa Birchall-Scott presented a paper on plans for the forthcoming 2015 People Survey and provided an update on the 2014 People Survey and related action plans. The CET heard that the prior to the launch of the annual People Survey on 1 October 2015 an extensive communications plan would be implemented. The CET heard that from July 2015 the People Survey Steering Group will meet bi-weekly, and the People Survey Focus Group would meet on 26 July and then monthly. Moreover, trade union representatives have expressed a wish to become involved with the People Survey, which was welcomed.

10.2 The CET welcomed the update on the preparatory arrangements and acknowledged the need to encourage a higher survey response rate by feeding back on both corporate and divisional progress in relation to last year's feedback. A further update including more detail on the communications planned will be given to the CET at its meeting in September.

## **11. Business continuity (CET/15/165)**

11.1 [redacted] and [redacted] of Policy Division updated the CET on Business Continuity and work on Business Impact Analyses. The update covered work on business continuity across the Agency since July 2014 and in particular work carried out by divisions on the Business Impact Analyses. The CET heard how this would feed into the Strategic Business Impact Analysis.

11.2 The CET reviewed the Tier 1 activities and functions and made a number of suggested amendments. These included the need to include specific references to medical devices, on the list. The CET thought that, while acknowledging that pandemic flu was a well-defined category, other emerging diseases and their impact on the Agency still required further consideration. Stephen Inglis said he would discuss this matter further with colleagues. The CET thought that further work was required on categorising the Tier 1 in order to get the right balance. The CET heard that work would start soon on drafting a Strategic Business Impact Analysis on Tier 1 activities and functions. At the same time, Information Management Division will draft an IT Business Continuity/incident plan, while Communications Division will draft a Business Continuity Communication Plan. Also, work will begin on drafting divisional business continuity plans.

11.3 The CET asked that before the draft Strategic Business Impact Analysis returns to the CET for discussion one of the CET's monthly mini away days should be given over to a discussion of business continuity. The CET asked that a scenario be devised for the CET to test the current draft Tier 1 activities. The CET also asked that lessons be learned from an incident that caused major disruption to public and commercial organisations in the Holborn area in April 2015. The CET heard that Agency would be kept informed of the lessons learned from such incidents by the DH Business Continuity Working Group.

**Action:** (i) CET Mini Away Day (date to be advised) to be given over to business continuity; (ii) Stephen Inglis to discuss with NIBSC colleagues how emerging diseases should be reflected in the Tier 1 activities

## **12. Off-payroll workers (CET/15/166)**

12.1 [redacted] and [redacted] presented a paper on the Cabinet Office's requirements for government organisations employing off-payroll staff. This follows the widespread use of personal service companies in sectors of the economy where individuals establish themselves as companies in order to pay lower tax, and some well publicised cases of senior public servants incorrectly using this route. The HMRC rules say that all such people are "employees" whatever their company status because the service purchased relates to them as an individual. The CET heard that the issue is the need for employers to obtain assurance that all temporary and interim contractors are paying PAYE and NICs on their earnings. The CET heard that the National Audit Office had refused to sign off the Agency's accounts until assurance was given about one interim contractor's earnings and tax affairs and one DH organisation had been fined £0.5m. MHRA must now check that temporary staff are on the relevant employment agency's payroll, with copies of the payslips being provided to Finance Division every three months as proof. The CET noted the Cabinet office's guidelines and agreed that they must be implemented to ensure the Agency's compliance.

## **13. 3<sup>rd</sup> floor accommodation – costs and savings review (CET/15/167)**

13.1 Peter Commins and [redacted] gave an update on the final costs associated with the Agency's move from three to two floors at 151 Buckingham Palace Road and the potential future savings that will flow from the loss of the 3<sup>rd</sup> floor, a spend of £700,000 and savings over the remaining 6 years of the lease of £24m. The CET noted the report and welcomed the update. The CET asked that further consideration be given to how communal facilities for staff at BPR could be improved, the cost of which could be shared with other tenants.

13.2 The CET observed that as the Agency's lease on its London offices will expire in 2021, preparatory work should begin soon to help inform an initial discussion by the CET on possible options and likely timeframes. Peter Commins agreed to take the lead on this work, with a paper coming to the CET at the end of 2015 or early 2016.

**Action:** (i) Accommodation Working Group to consider what communal facilities could be improved. (ii) Peter Commins to lead work on preparing an options paper for the 2021 accommodation move

**14. Finance and Procurement Report (CET/15/168)**

14.1 [redacted] presented the monthly Finance and Procurement report for the month of May and the year to 31 May. The CET noted the agency's total operating surplus for the year to 31 May of £5.0m against a budgeted surplus of £1.0m. The operating surplus comprised £2.4m, £2.0m and £0.6m for the regulator, NIBSC and CPRD respectively. A major component of the Agency's performance was MHRA (Regulator) income, particularly from DCP RMS, which is £1.3m (47%) above budget, and NIBSC income, particularly income from flu standards, which is £1.3m (248%) above budget.

14.2 The CET noted the Statement of Financial Position (SFP) and the analysis and illustration of debtors, receipts and payments on account. On the SFP, the most significant movement to note from April to May 2015 was the decrease in "other trade receivables" (debtors) due to the commencement of the collection of the 2015/16 Service Fee income in the month.

**15. Review of cross-agency groups (CET/15/179)**

15.1 The CET considered a short paper on the review of cross-agency groups, which was presented by Ian Hudson. The CET agreed it was important to keep a regular overview of the Agency's cross-groups, to ensure that when they had completed their work, they must be stood down, or if their work could be discharged more effectively, they should be subsumed into other groups. Ian Hudson asked that CET members review the list of groups and send any updates or changes to Michael Darbyshire in Directorate.

**Action:** CET directors to send any suggested changes to the list of cross-agency groups to Michael Darbyshire in Directorate.

**INFORMATION****16. NIBSC SMT Report (CET/15/169)**

16.1 This was note by the CET

**17. CPRD SMT Report (CET/15/170)**

17.1 This was noted by the CET.

**18. Volunteering Policy and Job Evaluation (CET/15/171)**

18.1 The CET formally noted the agreed position it took at the CET forward look meeting in 22 June 2015 on Volunteering Policy and Job Evaluation.

**19. Draft minutes of the 30 June Regulatory Group meeting (CET/15/172) and final minutes of 19 May Regulatory Group (CET/15/173)**

19.1 These minutes were noted by the CET.

**20. Updates from Cross-Agency teams**

20.1 These were all noted.

**Information Management Governance Board (June final) - CET/15/174  
Information Management Governance Board (July draft) - CET/15/175**

**Finance Sub Committee meeting (May final - CET/15/176)**  
**SOP Working Group (June draft - CET/15/177)**  
**Health and Safety (next meeting 3 September)**  
**Audit and Risk Assurance Committee (draft 22 Junes awaiting clearance)**  
**Risk Management & Audit Liaison Group (next meeting 9 September)**

**21. Agreement of 11 August CET agenda (CET/15/178)**

21.1 The agenda was agreed.

**22. AOB**

22.1 The CET watched a video clip of George Freeman MP, Minister for Life Sciences, launch the Yellow Card app earlier in the day (14 July).