Medicines & Healthcare products Regulatory Agency

Minutes

Title of meeting	Corporate Executive Team formal monthly meeting
Date	31 August 2016
Time	09.00 – 13.00
Venue	RT-410, BPR
Chair	Ian Hudson
Attendees	CET

CET Attendees

Ian Hudson	Chief Executive (Chair)
Peter Commins	Chief Operating Officer
Rachel Bosworth	Director of Communications
[Redacted]	deputising for Director of National Institute for Biological Standards & 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
John Quinn	Director of Information Management
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
Richard Humphreys	Deputy Director of Finance

Additional attendees
Andy Gregory (Policy) for item 4: Post-EU referendum – update and discussion
Mick Foy (VRMM) for item 5: Overdoses / National Poisons Information Service
Jan MacDonald (VRMM) for item 6: Strategic Direction for Patient Information
Patience Wilson (Policy) for item 7: Working with the Devolved Administrations, and item 8: Regulatory Policy Committee
Beryl Keeley (VRMM) for item 18: E-cigarettes update
[Names redacted under section 40 of the FOIA (personal data)]

1. Apologies and Announcements

1.1 Apologies were received from June Raine and Christian Schneider.

2. Draft minutes of the 9 August Corporate Executive Team meeting (CET/16/223) including table of actions and final minutes of the 12 July Corporate Executive Team (CET/16/1224)

2.1 The draft minutes were agreed. The CET reviewed and provided updates on the table of actions. The final minutes of the 12 July meeting were noted.

3. Draft minutes of the Regulatory Group meeting of 19 July 2016 (CET/16/225) and final minutes of 23 June (CET/16/226)

3.1 The draft minutes of the Board meeting of 19 July were noted, while the final minutes of the Board meeting of 23 June were noted.

STRATEGY

4. Post EU Referendum – update and discussion (CET/16/227)

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

5. Overdoses / National Poisons Information Service (CET/16/228)

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

6. Strategic Direction for Patient Information (CET/16/229)

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

7. Working with the Devolved Administrations (CET/16/230)

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

8. Regulatory Policy Committee Paper (CET/16/231)

8.1 Patience Wilson presented a paper to inform the CET and the Board of the activities of the Regulatory Policy Committee (RPC) and its relationship with the Agency. The CET noted that post implementation reviews do not include direct implementation of EU legislation – it is in relation to UK implementing legislation. The CET also queried that, looking to the future, if the Agency might need to recreate our own pharmaceutical legislation, whether the RPC would be looking for us to reduce burden even further than the existing legislation; and noted that the Agency will need to demonstrate that burden has been taken in to account. Is not, though, the RPC's role to dictate policy.

9. Companion Diagnostics and Genomics (CET/16/232)

9.1 [Name redacted under section 40 of the FOIA (personal data)] presented a paper on companion diagnostics and genomics. Phase 1, development of a draft strategy, has been completed. The CET noted the activities and progress that has been made in phase 1. The aims for companion diagnostic in-vitro diagnostics (IVDs) are to create a recognised centre of excellence for UK clinical trials to generate clinical evidence which enable access to worldwide markets. The UK is leading in Europe on the regulation of companion diagnostics. If we wish to continue to be leading influencers of science, quality and regulation, then we need to build on that lead. The Agency should aim to support regulations and development of companion diagnostics and medicines. The CET were presented with a projection of net return per year for clinical trials; with the requirement of a small investment beforehand in the form of training plans. The CET noted that because companion diagnostics are a relatively new area, this will create an opportunity for the MHRA to lead in this area to develop

guidance and scientific advice for devices and medicines, which would form a unique selling point for the Agency.

9.2 The CET agreed that this is an area in which the Agency should invest in; and this type of work should be reflected in the Agency's response to Brexit to showcase how the MHRA is at the forefront of difficult regulation of new areas such as this. A fair amount of investment will be required to train up assessors for this, which will be pan-divisional. There may also be links with other outside organisations to share training resources. Making the UK attractive for clinical trials involving companion diagnostics would involve other parties and the group was encouraged to discuss this further with the DH R&D team.

10. Operational Transformation (CET/16/235)

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

GOVERNANCE & DELIVERY

11. Finance and Procurement Report (CET/16/233)

11.1 The F&P report showed a healthy start to the year; with the Regulator operating at a surplus of £17.5m, NIBSC at a surplus of £2.1m, and CPRD at a surplus of £0.8m, all above the budgeted surplus. The £100m super dividend was paid on the 20 July 2016 with the normal dividend to be paid in September 2016; as shown in the statement of financial position which is £127m from £216m. The Income Risk Assessment was reviewed following Brexit and the income streams most likely to be impacted by Brexit have been identified. This was debated at the finance subcommittee.

12. Training Needs Analysis (CET/16/236)

12.1 [Name redacted under section 40 of the FOIA (personal data)] presented a paper on a Training Needs Analysis (TNA) which considered what challenges the agency, divisions and teams faced, that could be resolved through training not currently in place, and to identify any pan agency needs that can be prioritised and planned over the next one to three years. The HR business partners conducted a high level workforce planning activity to collate high level skills required going forward, which haven't been captured in current training plans. At this stage the TNA is at a high level; and will constantly evolve given future challenges such as Brexit and genomics work. The next step is to drill down further to pull together priorities and numbers by division, and also for pan-Agency figures, to identify potential costs as this is in addition to the current training budget. A piece of work has also been proposed on management and leadership training, to review each of the different types of managers within the Agency and identify their training needs. The CET noted that the TNA results list could be prioritised a bit more. CET noted that traditionally divisions have underspent on training budgets; therefore there is budget available to pay for the prioritised training needs. CET confirmed they are content with the direction of travel; that work should continue with divisional directors to put in a training plan in place with associated budget, and report back to CET in 1 years' time.

13. Recognition and Reward (CET/16/237)

13.1 Vanessa Birchall-Scott presented a paper on recognition and reward; specifically linked to improving morale and performance. Recognition and related reward can be both financial and non-financial. There is an opportunity to consider an additional financial reward for delegated staff, by way of a voucher available from the new My Lifestyle Civil Service benefits portal. In addition to this there is the suggestion of promoting the benefits of positive

feedback and recognition with our managers in a variety of ways and considering further opportunities such as the voucher being accompanied by a letter of recognition and possibly a small, divisional ceremony of some kind. Use of customer feedback and broader testing out of an agency wide scheme/ceremony of some kind, along with use of new IT capabilities are also proposed for further consideration. Vanessa suggested a process in the paper for the proposals.

13.2 The CET agreed that all managers should be reminded of the importance of recognition and informal feedback on a regular basis; HR will explore options for this. The CET noted that consideration should be given to whether the vouchers will be taxable; and consideration should be given to the value of the voucher as it is a small amount; £25 or £50, perhaps just settling on £50. CET questioned whether it was necessary to stick to15% of staff suggesting a higher level would be acceptable. Sign off should be at unit manager level. The CET also agreed that further consideration needed to be given to whether there should be an Agency wide recognition/award scheme and HR will consult with Divisional SMTs.

14. Market Pay Supplement (CET/16/238)

14.1 [Redacted under section 43 of the FOIA (Commercial interests)]

15. Agreement of team briefing notes (CET/16/0240)

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

REGULATORY GROUP

16. E-cigarettes update (CET/16/241)

16.1 Beryl Keeley presented an update on progress with the operationalisation of the Competent Authority role for e-cigarettes. Well over 300 notifications have been received to date. Companies have been submitting data; the Commission's reporting tool is limited in its functionality but progress is being made on this. The system has been set up in a way which will not require much resource to manage notifications. A small number of vigilance reports have been received; and work has also been ongoing with Trading Standards. The CET thanked the team for their progress and agreed to progress with the Agency's IT developments despite the uncertainty caused by delays to the EU system. It noted that allocation of project costs was being reviewed to take account of IT developments. The CET noted that work has been done to make it easy for companies to notify, and the MHRA expects companies to comply. If the Commission reporting tool is not available by the deadline, this will delay MHRA work; however workarounds such as publishing a list of notified companies will be considered.

17. Devices fees update (CET/16/242)

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

INFORMATION

18. NIBSC SMT update (CET/16/244

18.1 The minutes from the NIBSC SMT update from August.

19. CPRD minutes – deferred to October

19.1 The CET noted that the minutes for the next meeting of the CPRD Executive Committee will be heard at the October CET meeting.

20. Updates from Cross-Agency teams

20.1 These updates were noted by the CET.

Information Management Governance Board (August. final)	CET/16/246	Peter Commins
Finance Sub Committee meeting (16 July final)	CET/16/247	Peter Commins
SOP Working Group (6 June. final)	CET/16/197	Gerald Heddell
Policy and Procedures Working Group (next meeting 31 August)		
Health and Safety Strategy Group (next meeting 2 September)		
Audit and Risk Assurance Committee (17 July draft)	CET/16/249	Peter Commins
Risk Management & Audit Liaison Group (14 July draft)	CET/16/250	Peter Commins
Equality and Diversity Group (next meeting September)		Vanessa Birchall-Scott

21. Agreement of 4 October 2016 CET agenda (CET/16/252)

21.1 The CET agreed reviewed and commented on the draft agenda for the 4 October CET meeting. It was agreed that a number of items had still to be confirmed; relevant directors would advise Directorate.

22. Agreement of 20 September 2016 RG agenda (CET/16/253)

22.1 The CET agreed reviewed and commented on the draft agenda for the 20 September RG meeting.

23. AOB

23.1 Ian Hudson thanked Peter Commins and Mark Wilson on their enormous contribution to the CET on their last meeting.