

22 March 2018

Authority Meeting Report

1 Declarations of Interest

There were no interests declared.

2 Interim Review

The interim review of the strategic plan is scheduled for 26 April at 1:00 pm. The Chair and two Board members will participate in a workshop with the Director of Quality, Scientific Affairs and Communications (QSAC).

3 Health and Safety

The Chief Executive provided an update on the recent office closure for two days due to red weather warnings. While a power failure occurred, all IT systems were operational. Business continuity procedures had been recently updated and were effective. Text alerts were shared with all employees.

4 Risk management

The Audit and Risk Committee recommended the business risk review report to the Authority. The Committee Chair provided a summary of the changes to the risk register following the review. The Chief Executive outlined that internal processes for risk management changed in 2017. Department management teams were trained in the risk management process so that both the management committee and departments have responsibility for the identification and assessment of risks. It was highlighted that the changing risk scores reflect the changing environment. This is a living document and further updates will be provided.

5 HPRA Updates (such as changes to legislation, competencies and terms of reference)

There were no issues to report.

6 Chief Executive's Report

The Chief Executive briefed the Authority members including an update on the Freedom of Information High Court case relating to scientific animal protection inspection reports. The Chief Executive will provide a further update once available.

7 Eolas Update

The current status is that the first phase (wave one) of the EOLAS project for Veterinary Sciences has now been completed and is operational within the department. Continued support is being provided as part of normal ICT operations.

22 March 2018 1

The second phase (wave 2), covering the implementation for human medicines, clinical trials and classifications is progressing well. Wave 2.5 covering scientific analysis and classification is under analysis and due for completion later in the year. Project costs remain within the agreed budget.

8 Quarterly Review of the 2017 Service Plan

The Q4 report on progress against this years' service plan was presented by the Director of QSAC. The achievement of targets for all activities and progress against targets for the key priorities for 2017 were outlined.

The RAG (red, amber, green) status shows activities that are complete, on target, not due to be started, behind target or delayed. Overall, 85% of activities are complete, or on track with activity is ongoing. 12% of activities are minimally delayed, many due to external factors and none critical.

A number of organisational strategic approaches to minimise the impact of Brexit were discussed.

9 Strategic and Subsidiary Plans

The 2017 progress report on the HPRA strategic plan objectives and actions was presented by the Director of QSAC. The supporting subsidiary plans for communications and scientific affairs were also presented. The Authority members expressed an interest in supporting future outreach plans. It was queried if social media updates could be included in the media updates. The HR and Change strategy and aspirations will be formally presented at the May meeting.

This review process allows the organisation to measure performance against key indicators and provides for updates to the Board. It also forms part of the organisations performance delivery agreement with Department of Health.

It was agreed that the documentation presented demonstrates the progress within the new QSAC department and the hard work of the director and her team. The materials will prove very useful to the Chair and the participating Authority members for the scheduled strategic plan workshop due to take place on 26 April.

10 Review system of Internal Controls

The Chief Executive provided an overview of the system of internal control that operates in the HPRA and provides the basis for the Audit and Risk Committee and the Authority's annual review of the effectiveness of the system of internal control. It was agreed that the HPRA has a strong system of internal control. Controls are adequate and were operating effectively for the year ended 31 December 2017.

11 Vision for the New Medical Devices Department

The newly appointed Deputy Director, Dr Niall MacAleenan, presented an update on medical devices regulation in addition to his vision for the new Medical Devices Department under his remit. Niall was congratulated on his appointment and commended on his planned approach.

22 March 2018 2

12 Agenda for Meeting with the Secretary General

The Chair of the Authority and the Chief Executive will meet with the Secretary General of the Department of Health on 28 March. The draft agenda was shared with the members for comment. It was proposed that the review of the scientific committees should be raised at the meeting as the outcome may require legislative change in the future. The Chair and the Chief Executive agreed to add this to item 4 on the agenda: *Pending legislation across the health product areas*.

13 Succession Planning

The Chair provided a verbal update on succession planning.

14 Discussion on Preparation for June Away Day Meeting

It was agreed by all that the Management Committee should join the Authority members for an interactive session at the Board away day in June. A facilitator will be arranged for the day and the topic for discussion will be opportunities and challenges in becoming The Regulator of Tomorrow. A Deloitte report on the topic will be circulated to members and management committee after the meeting for consideration.

Post meeting note: https://www2.deloitte.com/content/dam/Deloitte/tr/Documents/public-sector/Regulator-of-tomorrow vFINAL.pdf

15 Committees

Audit and Risk Committee - 22 March 2018

The Chair of the Audit and Risk Committee provided an update on the meeting held earlier that day.

16 Finance

The Management Accounts for December 2017 and January 2018 were noted.

17 Licensing Activities

The tables of licenses approved by the Management Committee during the period 26/01/18 to 16/03/18 were noted by the Authority.

18 Authority Meeting Dates 2018

The next meeting of the Authority is scheduled for Wednesday, 16 May at 2:00 pm. It was agreed the Secretary would send a reminder to all members.

18 IPPOSI Video

It was stated that a link to the IPPOSI patient education programme video, which HPRA colleagues contributed to, would be circulated after the meeting.

22 March 2018 3