

15 March 2017

Authority Meeting Report

1 Declarations of Interest

There were no conflicts of interest declared.

2 Risk Management

The Risk Register was reviewed.

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

It was noted that the terms of appointment of Dr. Brangan and Mr. Higgins have been extended to 31/12/19. It was also noted that the Health Miscellaneous Provisions Act 2017 was enacted on 16 February 2017. It was outlined that the Code of Conduct and Conflict of Interest policies have been updated to reflect the Code of the Practice for the Governance of State Bodies 2016 guidelines (for the former), and the EMA's conflict of interest policy and the HMA's Guide to Managing Declarations of Interests (for the latter). The amendments were noted and the documents adopted.

4 Chief Executive's Report

The Chief Executive had circulated her report in advance of the meeting and the members of the Authority were invited to comment and ask questions. An overview was provided on the response to the HPRA report, Cannabis for Medical Use – A Scientific Review on 10 February. It was noted that the Department of Health is setting up a group in relation to medicinal cannabis for the purpose of implementing the access programme outlined within the HPRA report. The group is to include representatives from the HPRA, clinicians from the relevant therapeutic areas and patient representatives.

The finalisation of a Mutual Recognition Agreement (MRA) for GMP inspections between European and US authorities was noted and commended as a significant development in terms of more effective utilisation of collective regulatory resources. The HPRA will be assessed under the HMA's Joint Audit Programme (JAP) in May. The US FDA will be in attendance. The MRA will be formally implemented in Q4 2017.

5 Audit and Risk Committee – 15 March 2017

The meeting agenda was noted. The Chair of the Committee provided an overview of the matters discussed at the meeting including: the Statement of Internal Control, the Management Letter from the C&AG for 2016, the Code of Practice for the Governance of State Bodies for 2016, and the Risk Register. The Committee also reviewed the Chair's comprehensive report to the Minister for Health. Additionally, the Committee reviewed the management accounts for October, November and December 2016, and January 2017.

6 Advisory Committee for Medical Devices (ACMD) – 6 March 2017

The Chair's report was noted. The Chair of the Committee provided an overview of the matters discussed at the meeting including medical devices vigilance and market surveillance, ongoing inspections and assessments, legislation and policy primarily focussing on the implementation of the new medical devices legislation. The Committee also received a presentation from a Committee member in relation to his role as a consultant vascular surgeon/Dean of the RCSI.

7 Medical Devices Thematic Discussion

An overview was provided of the proposal for implementation of the revised medical devices Regulations at European, national and HPRA level. The medical devices structure in HPRA was outlined. An early analysis of resource requirements, pressure points, considerations, challenges, opportunities, key actions and next steps was discussed, and the members agreed that a project team/working group should be appointed.

8 EMA Bid Update

An update on the EMA bid to relocate to Dublin was provided. The work of the interdepartmental committee in relation to the proposal was outlined.

9 IT and Business Services: Eolas Project

It was noted that the Eolas project is progressing well. The members watched a video which provides an overview of the new system. The members were complimentary of the work to date.

10 HR and Change: Strategic Outturn 2016

The HR and Change strategic outturn for 2016 was noted by the members.

11 Business Planning

The members noted the Service Plan update report for Q4 2016 and the Strategic Plan 2016-2020 annual progress report. The staff were commended on the good work to date.

12 Financial

The members noted the management accounts for October, November and December 2016 and for January 2017. The members reviewed and approved the Statement of Internal Control as recommended by the Audit and Risk Committee.

13 Licensing Activities

The tables of licences approved by the Management Committee during the period 20/01/17 to 01/03/17 were noted by the Authority.

14 The Chair's Annual Report to the Minister

The members adopted the above document.