HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

6 December 2018

Authority Meeting Report

1 Declarations of Interest / Conflicts of Interest

There were no interests declared.

2 Chief Executive's Report

The Chief Executive provided clarification on her appointment as Co-Chair of the Competent Authorities for Medical Devices (CAMD) / Heads of Medicines Agencies (HMA) joint working group. In light of innovation, convergence and other emerging issues, this is a key focus within the network and is a good investment of time for the HPRA. Through this cooperation, there is a specific opportunity for CAMD members to observe the workings of the more established medicines network.

An update on medical cannabis was provided. The Department of Health is progressing the establishment of the access programme.

The Authority commended the very positive outcome of the Zero Gains anabolic steroids campaign and that its target market penetration was quite impressive. A future re-run of the campaign was supported by the Authority.

It was requested that the Deputy Director of Medical Devices would present to the Authority at the January meeting to provide an update on the developments in the devices area.

The Chair of the Advisory Committee for Medical Devices (ACMD) provided update from the Committee on (1) spinal correction rods and (2) ALCL.

The HPRA HR and Change team were congratulated on winning Best Health and Wellbeing Initiative at the 2018 Legal Island Irish HRA Awards. Lynsey Perdisatt, Director of HR&C, was also congratulated on attaining the highly commended award for Best Leadership in HR.

3 Eolas Update

The Director of ICT and Business Services attended to provide an update on the Eolas project. The presentation reflected on the progress to date, future plans and interactions with the developers, Bearing Point (BP), which had occurred since the previous Authority meeting.

4 Service Plan 2018: Q3 Progress Report

This document was taken as read. The number of items on track / completed has increased. The majority of items listed as outstanding are currently being progressed.

5 Service Plan 2019

The Service Plan for 2019 was presented. Brexit is central to this. Other key activities include:

- An increase in outgoing procedures with development of clinical expertise envisaged.
- During 2019, the communications focus will include social media content, a repeat of the ZeroGains campaign and online educational videos.

- Outreach and engagement will feature, particularly with research organisations and innovators. Maintaining increased stakeholder engagement, particularly from safety, medical devices and human medicines perspective, will be a priority. Information days on key topics are scheduled, including a Brexit information day planned for Q1.
- The development of a comprehensive ICT and Business Services strategy, including consideration of transfer to cloud based storage.
- The completion of the Medical Devices department re-organisation will close out in early 2019, allowing for increased focus on the implementation of EUDR.
- The next strategic plan development will take place throughout 2019 with a new approach planned for this iteration.
- There are a number of carryovers from 2018 including the Clinical Trials Regulation, EUDR, the Falsified Medicines Directive and the new veterinary medicines legislation.
- The Learning Development Programme and the Management Development Programme will run through 2019.
- The main risks identified in the service plan relate to Brexit.

6 Crisis Management Review

A paper on the on-going HPRA crisis management procedure was presented. The review has been broad-based and in addition to incorporating on-going continual improvement processes, has reflected on case studies and crises, which have occurred in the wider health sector and associated lessons learned and applicability to HPRA. It also has taken into account crisis preparedness measures taken by other agencies with a relevant remit. The Authority commended the comprehensive and strategic approach that has been taken.

7 Budget 2019

The Deputy Chief Executive provided a summary of the 2019 budget, which was then recommended to the Authority by the Audit and Risk Committee and approved by the Authority.

8 Statutory Review of the Committees

The Chair of the ACMD provided an update on the progress of the statutory review of the scientific committees to the Authority. Both the Chair of the ACMD and the Chair of the Advisory Committee for Veterinary Medicines (ACVM) will attend departmental management meetings, to be piloted with the veterinary sciences and medical devices departments, in Q1 2019. The review will be finalised by mid-2019 with a view to sharing the proposal with the Department of Health after the June meeting of the Authority.

9 Agreed Meeting Schedule 2019

The proposed dates were agreed. It was suggested that an additional meeting may be required for April 2019, post the March 29 Brexit deadline. The Secretary will circulate potential dates for an April meeting.

10 Annual Report Media Launch

The HPRA annual report was published to the HPRA website on 3 October 2018. A hard copy was presented to each of the Authority members.

11 Committees

11.1 Audit and Risk Committee – 04/12/18

The Chair recommended the budget 2019 to the Authority following extensive review at the Committee meeting on 4 December.

11.2 Advisory Committee Medical Devices (ACMD) – 26/11/18

An update from the meeting was provided by the Chair.

12 Finance

The Audit and Risk Committee had reviewed and noted the management accounts for October 2018. There were no additional comments.

13 Licensing Activities

The tables of licenses approved by the Management Committee during the period 21/09/2018 to 30/11/2018 were noted by the Authority.

14 Authority Meeting Dates 2019

The next meeting of the Authority is scheduled for Thursday, 24 January 2019. It was agreed the Secretary would send a reminder to all members.