HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

10 May 2017

Authority Meeting Report

1 Declarations of Interest

There were no conflicts of interest declared.

2 Reappointment of Board Members to 31/12/19

It was noted that Dr. Brangan and Mr. Higgins had received official confirmation of their reappointment to the Authority until 31 December 2019.

3 Medical Devices

It was noted that the members of the medical devices working group have been agreed in-house and that Mr. Higgins will contact to Prof. Horgan in relation to the matter prior to starting the process.

4 Health and Safety

There was nothing to report.

5 Risk management

There was nothing to report as the Risk Register had been reviewed at the March meeting of the Authority.

6 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 in relation to the development of an implementation programme for cannabis facilitated by the Department of Health. There are approximately 20 clinical experts members of the Group including a HPRA representative reviewing various products.

It was noted that the HMA's Joint Audit Programme (JAP) which is a benchmarking programme for European inspectorates is key to the upcoming Mutual Recognition Agreement (MRA) for GMP inspections between European and US Authorities. The HPRA is to be assessed under this programme the week beginning 15 May at which the US FDA will be in attendance. The MRA will be formally implemented in Q4 2017.

With regard to the national anti-microbial resistance (AMR) plan, it was noted that the HPRA is one of 20 organisations participating. The national plan is to be finalised with stakeholders in Q2 2017 and is in line with the WHO plan.

In relation to the Innovation Office, it was noted that approximately 45 queries are received each month primarily related to classification queries. The outreach programme with industry and academia is progressing well and the HPRA is liaising with the UK's Innovation Office.

It was noted that the Director of Human Product Monitoring is to attend the Oireachtas Joint Committee on Health on 11 May in relation to the HPV vaccine and will provide information regarding the safety monitoring role of the HPRA. Representatives from the National Immunisation Office, the HSE, the Department of Health and Prof. Mary Horgan (HPRA Authority member) have also been invited to attend.

7 Advisory Committee Veterinary Medicines (ACVM) – 5/4/17

The Chairman provided an overview of the meeting highlights including both a peer review of a veterinary product and an issue in relation to the environmental impact of zinc oxide containing products following a recent conclusion at CVMP. It is planned to phase out such products over a number of years which could have an impact on antimicrobial resistance in Ireland.

8 Brexit Impacts

EMA Relocation
It was noted that work is progressing on the interdepartmental committee in relation to the proposal for the potential EMA relocation to Dublin. It is anticipated that the relocation decision will be made by the end of 2017 and the EMA is required to be in its new location by April 2019 in line with the timeline for completion of Brexit negotiations.

Opportunities and Threats for the HPRA
The Authority reviewed the opportunities and threats for the HPRA arising out of Brexit. Strategically, the first aim or the organisation will be to protect medicines availability, the integrity of the national market and links with Europe. The second aim will be to capitalise on any opportunities that are available and increase assessment of centralised and decentralised products, increase inspections and expand the HPRA role in medical devices.

9 Eolas Project

It was noted that the Eolas project is progressing well and anticipated to go live on 29 May. It is expected that the system will be fully rolled out by Q1 2018. The members were complimentary of the work to date.

10 Development of International Networks

The Authority was provided with an overview of important HPRA involvement at an international level including: Heads of Medicines Agencies (HMA), European Medicines Agency (EMA), the International Coalition of Medicines Regulatory Agencies (ICMRA), the International Conference of Drug Regulatory Authorities (ICDRA) and the International Medical Device Regulators Forum (IMDRF).

11 Business Planning

The members noted the results of the Service plan for Q1 2017 with 98% of actions on track, completed or not yet due.

12 Finance

Management Accounts February and March 2017
The above management accounts were noted.

13 Licensing activities

Tables of Licenses from the 10/3/17 to the 28/4/17
The Authority noted the above tables specifying the licences approved by the Management Committee.