HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

3 December 2015

Authority Meeting Report

1 Declarations of Interest

There were no conflicts of interest declared.

2 Risk Management

The Authority was updated on the risk register and any changes to the register since it was last reviewed by the Authority.

3 Chief Executive's Report

The Chief Executive, Acting provided an overview of the main highlights of her report which were noted by the Authority:

- Activity levels, quality indicators and finances are at expected levels.
- Some recruitment had taken place in the last few months both to replace staff who have left and some additional new roles. It was recognised that a recovering economy and increased salaries in the private sector could impact on HPRA's ability to recruit and retain staff.
- Details of the register developed by the HPRA which allows those entitled to purchase emergency medicines under the, Medicinal Products (Prescription and Control of Supply) (Amendment) (No. 2) Regulations 2015 to place their name on the register if they fulfil the necessary requirements.
- Details of the meeting of the Competent Authority for Medical Devices (CAMD) which hosted by HPRA in Clontarf Castle at the end of November.
- An update on the Zambia contract.
- Confirmation the HPRA is subject to a High Court action seeking the withdrawal of the authorisation for Gardasil and the cessation of the roll out of the Human Papilloma Virus (HPV) vaccine among teenage girls in schools.
- Confirmation that the Article 20 European Medicines Agency (EMA) review of the HPV vaccine confirmed that the evidence does not support a causal link between the vaccines (Cervarix, Gardasil/Silgard and Gardasil-9) and development of Complex Regional Pain Syndrome (CRPS) and Postural Orthostatic Tachycardia Syndrome (POTS) which are related to the symptoms alleged in the Irish Court Case.
- The Authority was informed that Dr. Mike Morris, Director Scientific Affairs has retired after 28 years with the HPRA and that Dr. Caitríona Fisher is the incoming Director of the restructured Quality, Scientific Affairs and Communications Department.

4 Report on Eolas Workflow System

An overview of the Eolas project to date was provided. The benefits will include the fact that the seven current workflow / data base systems in the organisation will become fully consolidated under one standard system. It is believed that Eolas will deliver a "best in class" IT system among European regulatory authorities and will future proof the organisation while delivering

operational efficiency. It was also proposed that regular updates be provided to the Authority in relation to the progress of the project.

5 Committee Meetings

5.1 Audit Committee – 23 September 2015

The Chair of the Audit Committee provided an overview of the matters discussed at the meeting earlier that day. It was noted that the Audit Committee Annual Work Programme had been reviewed which was considered useful. Also noted was a list of the Finance standard operating procedures (SOPs) reviewed to date, the updated Audit Committee Terms of Reference and the fact that the 2015 draft Code of Practice for the Governance of State Bodies had been reviewed in detail to prepare for implementation once the Code is approved. The Risk Register was reviewed (see item 2 above). The 2016 Budgets, which were to be recommended to the Authority for adoption were reviewed as were the management accounts for October. The Audit Committee had met with a representative from the office of the Comptroller and Auditor General (C&AG) who had commented on the recent audit where the HPRA was found to be in full compliance as no significant findings had been identified and no Management Letter had been issued. It was noted that the C&AG itself would be auditing the organisation in 2016 rather than an outsourced C&AG firm as has been the case for the last few years.

5.2 Advisory Committee for Medical Devices (ACMD) – 30 November 2015

The Chair of the ACMD provided an overview of the matters discussed at its most recent meeting including a summary of safety notices, updates on various vigilance issues, vigilance signal detection, the AED media campaign and the HSE/HPRA e-Alert launch. Updates were also provided in relation to the NSAI designation assessment 2015, market surveillance, the fee based funding model for medical devices and the review of EU medical devices legislation. In addition, the ACMD was provided with an update in respect of the relevant EU working groups.

5.3 Advisory Committee for Veterinary Medicines (ACVM) – 30 September 2015

The Chair of the ACVM provided an overview of the matters discussed at the meeting on 30 September including the Anti-Microbial Sub-Committee, a peer review exercise and an update on CVMP referrals. The Committee also received updates on EMA and Heads of Medicines Agency (HMA) meetings and in respect of the proposed EU veterinary medicines legislation.

6 Anti-Microbial Resistance Report

The Authority adopted the Anti-Microbial Resistance Report produced by an expert Sub-Committee comprising of HPRA staff and members of the HPRA Advisory Committee for Human Medicines (ACHM) and the ACVM. The Sub-Committee was complimented on the report which is to be published on the HPRA website.

7 HPRA Strategy 2016-2020

The Strategic Plan 2016-2020 was adopted.

8 IBTS Report 2015

The Authority adopted the HPRA Report on the Irish Blood Transfusion Service for 2015.

9 HPRA Service Plan 2016

The Authority noted the 2016 Service Plan.

10 Financial

(i) Budgets 2016

The Authority reviewed and adopted the budgets for 2016 which had been recommended for adoption by the Audit Committee.

(ii) Management Accounts

The management accounts for August, September and October 2015 were noted by the members.

11 Licensing Activities

The tables of licences approved by the Management Committee during the period 18/09/15 to 19/11/15 were noted by the Authority.

12 Authority Meeting Dates 2016

The Authority noted the meeting dates for 2016.

13 AOB

The Chairman's Vote of Thanks

As this was the last meeting of the current Authority, the Chairman thanked the Authority members and the Chairs of the Committees for their dedication and commitment during their terms of office.