HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

1 December 2016

Authority Meeting Report

1 Declarations of Interest

Professor O'Driscoll stated that she is the Vice-Chair of Regulatory Science Ireland (RSI).

2 Risk Management

The Risk Register was reviewed at the September meeting of the Authority.

3 Chief Executive's Report

The Chief Executive had circulated her report in advance of the meeting and the members of Authority were invited to comment and ask questions:

- It was noted that the visit by the Zambian Medicines Regulatory Authority (ZAMRA) to the HPRA had gone well and the project is progressing. An experienced member of the HPRA's Good Manufacturing Practice (GMP) inspection team is based in ZAMRA for the next 3 months to further assist with training and development.
- With regard to the medicinal use of cannabis, the Chief Executive had been invited to contribute to an Oireachtas Joint Committee on Health to provide an overview of the current regulatory situation. The HPRA has also been asked for formal expert advice in relation to the matter.
- With regard to the HPV vaccine, it was noted that the uptake has reduced as a result of negative publicity. The RCPI has agreed to facilitate a number of workshops to more positively promote the HPV vaccine. The workshops will include participation from the HSE, the Department of Health (DoH), the HPRA, oncologists and other clinicians.
- An overview was provided of the Irish bid for relocation of the EMA following Brexit. It was noted that the HPRA is participating in a recently established interdepartmental committee with other key stakeholders such as the Department of Health, the Department of the Taoiseach and the IDA to progress the bid. The Minister for Health is to meet the Executive Director of the EMA in January.
- The Authority members extended their congratulations to HPRA staff in relation to the recent medical devices information day.

4 Committee Meetings

4.1 Advisory Committee for Human Medicines (ACHM) – 1 December 2016

The Chair of the Committee provided an overview of the highlights of the meeting which included updates in respect of pharmacovigilance, reclassification/switching of medicines, interchangeable medicines and licensing activities. Year to date updates from the Clinical Trials Subcommittee and the Herbal Medicines Subcommittee were also provided to the ACHM. In relation to the review of cannabis derived medicines, it was noted that at the request of the Minister for Health the HPRA has agreed to provide an expert opinion on medicinal cannabis. To

facilitate the request a working group is to be set up. The working group is to report back to the ACHM and then the Authority in January 2017 before submitting a report to the Minister.

4.2 Advisory Committee for Medical Devices (ACMD) – 28 November 2016

The Chair of the ACMD provided an overview of the matters discussed at its most recent meeting which included medical devices vigilance and market surveillance, a notified body update, legislation and policy. It was noted that the HPRA presented a discussion document to create specific expert domains within the ACMD such as software experts, in-vitro diagnostic experts etc. It was proposed that these domain members would be proactively consulted on general issues relevant to their specialist area rather than case specific work. This would include, for example, the development of guidance, policy issues etc. The document has been circulated for further comment. The Committee also received a presentation from one of the Committee members in relation to his work in the Regulated Software Research Centre in Dundalk IT.

4.3 Audit and Risk Committee – 25 November 2016

The Authority noted the agenda of the above meeting. The Chair provided an overview of the highlights of the meeting. The budgets for 2017 were reviewed by the Committee in detail and recommended for approval by the Authority. The Committee reviewed revised Audit and Risk Committee documentation in line with the Code of Practice for the Governance of State Bodies 2016 including the Terms of Reference, the Audit Charter and the Check List. The Committee also reviewed the Work Plan for 2017 in addition to the management accounts for August and September 2016.

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

The Chair of the ACVM provided an overview of the matters discussed at its most recent meeting which included the HPRA Strategic Plan 2016-2020, pharmaceutical issues, such as peer review of the assessment of a pour-on solution for cattle, sheep and goats, the report on pending referrals to the CVMP and the CVMP Strategy on Antimicrobials 2016-2020. Also discussed were pharmacovigilance and inspectorate issues, such as the pharmacovigilance annual report 2015, the CVMP opinion on Velactis, the report on the consumption of veterinary antibiotics in Ireland during 2015 and licensing tables. In addition, EU updates and reports of meetings were provided to the Committee.

5 Overview of Changes to Medical Devices Legislative Framework

The Chair of the ACMD provided an overview of the changes in the medical devices legislative framework and how the HPRA is positioned to respond to these changes. Implementation of the new legislation will commence at the end of 2017 and will finish in 2022 for in-vitro diagnostics. The HPRA has taken a leading role at European level in relation to medical devices where it has a strong reputation. The importance of medical devices to the Irish economy cannot be underestimated with 18 of the top 25 global device manufacturers based here, 29,000 people employed across 450 companies, and exports to the value of €12 billion (12% of European industry). Ireland also has 4% of the global market and 41% of the medtech innovation market.

In order to meet the challenges of the new legislation, the HPRA will conduct a detailed internal review of its existing resource, processes and operations to ensure they are appropriately

developed to fulfil responsibilities under the new Regulations. A detailed implementation plan and a proposal for further activity review will be presented to a future Board meeting.

6 Succession Planning – Thematic Discussion

A discussion on succession planning was led by two Authority members. In relation to the HR & Change Strategy 2016-2020 goal of career development, the focus was on succession planning including a review of key existing roles and the establishment of a long term career framework and a short term risk based approach to the issue. The risk based approaches for key roles, known absences and critical skills would be collated and presented to the Management Committee to inform the resourcing decisions over the next 24 months.

It was noted that the organisation is starting this process on a firm foundation as the HR & Change strategic goals were devised following consultation with staff. The concept of succession planning has also been discussed with the HPRA section managers who will need support in critically reviewing their staff in this regard. Focussing on the employees, roles and skills that add value to the HPRA will benefit the organisation in the long run.

The Chair thanked those involved in leading the thematic discussion, including the HR & Change Director for her significant contribution, and complimented the work to date.

7 IBTS Report 2015

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

8 Business Planning

The Authority was provided with an overview of the Q3 Service Plan Report which demonstrates that the organisation is meeting its targets. The Authority also reviewed the finalised Key Priorities and Objectives for 2017 which is consistent with the 2016-2020 Strategic Plan.

9 Eolas

An overview was provided of the Eolas project to date. The project is proceeding well in line with the updated project plan set out in August. The roll out is on track to move from veterinary medicines to human medicines and then on to the inspection section and medical devices. System integration testing (SIT) has commenced and initial indications are positive. The timeline for go-live for the Veterinary Sciences department is end February 2017.

10 Corporate Governance: Board Evaluation 2017 Training Options

In line with Section 4.6 the Code of Practice for the Governance of State Bodies 2016, the HPRA Authority is required to *undertake an annual self-evaluation of its own performance and that of its committees. An external evaluation proportionate to the size and requirements of the State body should be carried out at least every three years*. The Authority reviewed a number of options for external self-assessment and selected an appropriate provider for 2017.

11 Licensing Activities

The tables of licences approved by the Management Committee during the period 16/9/16 to the 18/11/16 were noted by the Authority.

12 Authority Proposed Meeting Dates 2017

The Authority noted the proposed meeting dates for 2017. It was agreed that the Secretary circulate the dates again and if anyone has any difficulty attending to inform the Secretary as soon as possible.

13 Regulatory Science Ireland (RSI)

(Professor O'Driscoll left the room for this item).

The Authority considered that a longer term training initiative with the RSI might be appropriate.