HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

25 January 2017

Authority Meeting Report

1 Declarations of Interest

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

2 Payment for Authority Members

It was noted that the matter of payment for Authority members has been included in the Health (Miscellaneous Provisions) Bill 2016 which should be finalised by the end of Q1.

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

The members reviewed and approved the following documents, updated in accordance with the 2016 Code of Practice for the Governance of State Bodies, which were recommended for approval by the Audit and Risk Committee:

i. Audit and Risk Committee Charter
ii. Audit and Risk Committee Terms of Reference

4 Chief Executive's Report

An overview was provided of the HPRA sponsored winning project at the Young Scientists Exhibition. This related to a wrist band for patients with a Radio-Frequency IDentification (RFID) strip containing details of their medication history.

The Authority noted the update provided on the EU Commissions' intended approach to the implementation of the revised legislative framework for medical devices in Europe. The Commission has indicated that its primary focus in terms of the application of resources will be the development of implementing and delegated Acts, and not on a co-ordination and leadership role.

The HPRA hosted a meeting with ZAMRA, the Zambian medicines regulator, to help build regulatory capacity in Zambia. The European Commission posted an update on the bilateral meeting between the HPRA and ZAMRA, which took place in the HPRA offices, on its Facebook page, citing it as the first ever visit by an African authority to a European regulatory body.

It was also noted that in early January, the EU Commission consulted with the Member States on the "Agreement on Mutual Recognition between the European Community and the United States of America, in order to amend the Sectoral Annex on Pharmaceutical Good Manufacturing Practices (GMPs)". This was discussed at the European Council's Trade Policy Committee on 13 of January. Achievement of a mutual recognition agreement for GMP inspections between the US and Europe is a hugely significant development and will afford significantly more effective utilisation of inspection resources by all parties.

5 International Conference of Drug Regulatory Authorities (ICDRA)

An overview was provided of the preparations for the prestigious World Health Organisation (WHO) ICDRA conference which the HPRA will be hosting in September 2018. It was noted that the conference is to run over five days. The WHO determines and manages the agenda and publishes the outcomes. The focus is on capability building for lower and middle income countries. It is anticipated that the designed website for the event will be ready by September 2017. It is expected that up to 400 delegates from 90 countries may attend. The Authority members were complimentary of the work undertaken to date.

6 EMA Bid Update

The HPRA is engaged with the interdepartmental committee on the Irish bid for the relocation of the EMA to Dublin with the Department of the Taoiseach, the Department of Foreign Affairs, the Department of Health (lead), the IDA and Science Foundation Ireland. The next meeting is to take place on 30 January. The Minister for Health and the HPRA Chief Executive, as part of a health delegation, have now visited the EMA and met with senior representatives including the Director General and the Deputy Director General. A meeting with Irish industry representatives outlining the approach being taken to the bid is planned and will take place in the coming weeks.

7 Eolas Project

An overview of the progress to date in respect of the Eolas workflow was provided to the Authority. The benefits of consolidating the HPRA's existing seven systems into one system, with cross-organisational harmonisation, are significant for long term efficiencies and resource utilisation. It was noted that excellent support is being provided to the project team from across the organisation. A live demonstration of the system was provided to the members who complimented the new system.

8 Medicinal Cannabis Report

An overview of work completed by the working group of experts, convened by the HPRA to discuss the matter of cannabis for medicinal use, was provided. The output of this work is a report for the Minister for Health which will be provided by the end of January 2017. The report was discussed by the Advisory Committee for Human Medicines (ACHM) on the 19 January 2017 and is now presented to the Authority for approval. The main findings of the report are that the HPRA cannot recommend medicinal use of cannabis for wide groups of patients and treatment of a broad range of conditions due to insufficient evidence of efficacy and safety concerns. However, if a Government policy decision is made to allow the medical use of cannabis on the grounds of societal and public interest, the lack of efficacy and safety data must be recognised and managed. The HPRA would also advise that should such a policy decision be made, it should limit the access to cannabis to specified groups of patients with the following medical conditions:

1. Spasticity associated with multiple sclerosis resistant to all standard therapies and interventions whilst under expert medical supervision;
2. Intractable nausea and vomiting associated with chemotherapy, despite the use of standard anti-emetic regimes whilst under expert medical supervision;
3. Severe, refractory treatment-resistant epilepsy that has failed to respond to standard anticonvulsant medications whilst under expert medical supervision.

Cannabis should only be made available for the treatment of the above conditions where patients have failed to respond to all other previous treatments including authorised and regulated medicines. Such patients should be under the direct supervision of an appropriately trained and experienced medical consultant. Use should be initiated as part of a 5-year pilot cannabis treatment programme where patients, pharmacists and doctors are registered, and utilisation data may be collected and monitored. This will allow the true needs of Irish patients for cannabis treatment to be determined.

The Chair and Authority were extremely complimentary of the quality of the report prepared in such a tight timeline and expressed their appreciation to all involved.

9 Communications Strategy Review

The members noted the outturn of the Communications Strategy for 2016.

10 Authority Calendar Review 2016 and Authority Calendar Plan 2017

The members reviewed an overview of the Authority compliance with the agreed 2016 calendar of activities and the calendar of activities for 2017 which was agreed.

11 Corporate Governance Board Evaluation

In line with Section 4.6 the Code of Practice for the Governance of State Bodies 2016, it was noted that 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*.

12 Financial

The members noted the management accounts for October and November 2016. It was agreed that they be recirculated at the next meeting following review by the Audit and Risk Committee.

13 Licensing Activities

The tables of licences approved by the Management Committee during the period 25/11/16 to the 13/01/17 were noted by the Authority.

14 Regulatory Science Ireland (RSI)

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

The potential for developing an educational partnership with RSI was discussed.

15 President of RCPI

It was noted that Professor Mary Horgan, Authority member, has recently been appointed President designate of the Royal College of Physicians Ireland. The Chair congratulated Professor Horgan on behalf of the members.