HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

28 January 2015

Authority Meeting Report

1 Declarations of Interest

There were no conflicts of interest declared.

2 Risk Management

There were no updates to report.

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

In respect of controlled drugs, the following Statutory Instruments were noted by the Authority: S.I. No. 571/2014, S.I. No. 583/2014 and S.I. No. 584/2014.

4 Chief Executive's Report

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

- The continuing success of the interchangeable medicines project whereby 44 active ingredients have been published to the interchangeable list was highlighted. Regarding the important area of reclassification of human medicines, a further list of potential reclassifications – from prescription to non-prescription pharmacy only and from over-the-counter to general sale – was developed and finalised. Engagement with the marketing authorisation holders in relation to the submission of associated reclassification applications has commenced.
- The medical devices team continues to provide ongoing support to the Department of Health relating to the negotiation of the medical devices regulatory proposals at a European level.
- Preparatory work is continuing for the development of the new workflow system which is to be named HPRA Eolas, following an internal competition.
- All staff, including single scheme pension staff, received pension benefit statements.
- Planning permission is being sought to provide lighting around the approved HPRA sign to be mounted on the side of Kevin O'Malley House.
- A representative from the HPRA attended the international summit and the plenary session of the International Coalition of Medicines Regulatory Authorities (ICMRA).
- The HR lead from the Department of Health met with the HPRA HR team and the feedback received was very positive.

5 Committee Meetings

5.1 Advisory Committee for Medical Devices (ACMD) – 23 January 2015

The Chairperson of the ACMD provided an overview of the meeting highlights which included details of the medical devices vigilance programme incorporating the continued follow-up in

respect of metal-on-metal hip implants, the National Standards Authority of Ireland (NSAI) joint surveillance audit, the HPRA medical devices information day and the proposed European regulations relating to general medical devices and *in-vitro* diagnostic medical devices.

6 Development of HPRA Strategic Plan 2016-2020

An overview was provided of the ongoing development of the strategic plan for the period 2016 to 2020. This included an outline of the various stages involved and the timeline for Authority engagement and approval. It was noted that staff at all levels and the members of the various scientific advisory committees are being invited to contribute to the plan. These consultations will be used as a basis for an initial draft to be reviewed by the senior management team. The plan will then go out for public consultation to HPRA stakeholders including those across the health system, the general public, industry, academia and government. An updated draft will be presented to the Authority for full discussion in July 2015 and with final approval expected in October/November 2015.

7 Verbal update from meetings with the Minister for Health and the Secretary General

The Chair and the Chief Executive met with Minister Varadkar on 28 January. The topics discussed included interchangeable medicines and switching/reclassification of medicines. The Minister recognised the contribution made by the HPRA in respect of the estimated €80m savings arising from the first year of operation of the interchangeable medicines list. The proposed introduction of medical devices fees in 2015 by the HPRA was also discussed. Additionally, the Chair and Chief Executive met with the Secretary General for a very productive discussion on various topics including HPRA staffing needs.

8 Financial

The management accounts for November 2014 were noted by the members.

9 Licensing Activities

The tables of licences from 28/11/14 to 16/01/15 approved by the Management Committee were noted.

10 Appointments to the Authority (Board)

An overview was provided of the new State Board appointments process whereby all interested parties are required to register their interest through the Public Appointments Service for final consideration by the relevant Minister. As the terms of office for five HPRA Authority members expire at the end of the year, it was recommended that members interested in reapplying register with the Public Appointments Service by June 2015 at the latest.

11 Authority Meeting Dates 2015

The Authority members noted the meeting dates for 2015.

12 Anti-Microbial Resistance (AMR)

It was proposed that the HPRA would recommend establishing a cross/joint committee on antimicrobial resistance at the next meetings of the Advisory Committee for Human Medicines and the Advisory Committee for Veterinary Medicines. It was also noted that the Chief Executive is representing the HPRA on the recently established National Intersectoral AMR Consultative Committee. Other members include the Chief Medical Officer from the Department of Health, the Chief Veterinary Officer from the Department of Agriculture, Food and the Marine, and representatives from the Health Protection Surveillance Centre, the Health Services Executive, the Food Safety Authority of Ireland and the farming sector.

13 Regulatory Science Ireland (RSI)

The Authority was informed of the upcoming RSI knowledge management conference being held in Dublin Castle from March 26 to 28. The members were invited to attend.