HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

23 September 2015

Authority Meeting Report

1 Declarations of Interest

There were no conflicts of interest declared.

2 Health and Safety

There were no health and safety items to report.

3 Risk Management

It was agreed by the Authority that a full review of the Risk Register would take place at its next meeting.

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

4.1 Authority Terms of Reference

The updated terms of reference for all the committees were approved subject to minor changes.

5 Chief Executive's Report

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

- The review of fees for medical devices and the status of the EU recast of the Medical Device Directives.
- Recent discussions with the Department of Health in relation to new competencies. The Authority approved the proposal that the HPRA implement the emergency medicines register required under the new statutory instrument to allow access to emergency medicines.
- An update on the Eolas workflow project with agreement that this would be discussed in more detail at a future meeting.
- The HPRA contribution to the recent visit to Ireland by the Chinese Minister for Health.

6 Committee Meetings

6.1 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 terms of reference were to be updated to reflect the rolling terms of appointment of the Authority members while the Audit Committee annual programme of work was also agreed. The Risk Register and a number of finance SOPs were reviewed. It was also noted that the HPRA is reviewing the draft Code of Practice for the Governance of State Bodies 2015 in preparation for the introduction of the revised Code.

7 Quarterly Meeting with Minister for Health

The Board was briefed on the quarterly meeting between the Minister for Health and the HPRA Chair and Chief Executive, Acting. A range of topics were discussed including the medical devices regulatory fees proposal, interchangeable medicines, the legal status of switching applications, medicines shortages and European oversight of the safety of medicines. The Strategic Plan 2016-2020, staffing challenges, the recruitment of a new Chief Executive and international / regulatory opportunities were also discussed as was the expiration of the terms of appointment for three members of the Authority at the end of 2015.

8 Service Plan Status Update

The Authority was provided with a Service Plan status update in respect of Q2, 2015.

9 Financial

The management accounts for June and July 2015 were noted by the members.

10 Licensing Activities

The tables of licences approved by the Management Committee during the period 26/06/15 to 11/09/15 were noted by the Authority.

11 Authority Meeting Dates 2015

The Authority noted the meeting dates for 2015.

12 Authority Meeting Dates 2016

The Authority noted the meeting dates for 2016.

13 AOB

The Authority was informed of a situation relating to medical devices made by the Brazilian manufacturer Silimed. It was noted that the HPRA, jointly with medical device regulators across Europe, had been advised of the suspension of the CE certificate for all medical devices made by Silimed.

The HPRA is investigating the matter in collaboration with other European regulators and has recommended that none of these devices should be implanted until further advice is issued. It has emphasised that to date there has been no indication that these issues could pose a threat to the implanted person's safety. The Department of Health has been informed.