HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

23 March 2016

Authority Meeting Report

1 Declarations of Interest

There were no conflicts of interest declared.

2 Matters Arising

There were nothing to report.

3 Health and Safety

There were no health and safety items to report.

4 Risk Management

It was noted that risk management would be discussed at the next Authority meeting in keeping with the Authority calendar.

5 Chief Executive's Report

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

- The HPRA has been asked by the Department of Health to take a role in co-ordinating the management of medicines shortages in Ireland.
- The registration scheme required under the emergency medicines legislation has been developed by the HPRA and is ready to be commenced when required.
- The HPRA has introduced a national scientific advice process as a six month pilot programme to provide scientific advice to pharmaceutical companies and others including academic and SMEs based in Ireland which the Authority supported. On completion, the pilot will be reviewed and further decisions on a wider introduction will be made at that point. It was noted that the Veterinary Sciences department may provide similar services based on the learnings from the pilot. This initiative supports the HPRA strategic goal to support innovation.
- Progress is being made in relation to the Zambia project. The Chief Executive and Deputy Chief Executive met recently with the WHO and the Gates Foundation to share insights into development needs in Africa.
- With regard to the medical devices legislation recast, progress is being made at a European level under the Dutch Presidency of the EU. However there are still a number of outstanding issues including liability of manufacturers, informed consent and genetic counselling. The national medical device fee proposal is also progressing. The HPRA is following up with industry on key outstanding issues and has submitted its proposal to the Department.
- The HPRA met a delegation of MEPs visiting Ireland.

- Work on Eolas project is continuing.
- A European review has concluded in respect of Silimed breast implants.
- In relation to the Gardasil High Court case, an applicant was not successful in seeking injunctive relief.
- April is Health and Wellness Month in the HPRA as part of the ongoing health and wellness strategy for the organisation.
- The Authority was informed that Dr. Jayne Crowe has recently been appointed as Director of Human Products Authorisation and Registration.

6 Audit Committee Meeting – 23 March 2016

The Authority ratified the composition of the Audit Committee: the newly appointed Chair, Mr. Pat Brangan, existing member, Professor Elizabeth Keane and new appointee, Mr. David Holohan. Mr. Brangan provided a brief overview of the meeting held earlier that day. It was noted that the Committee had reviewed the letter from the C&AG outlining the process for the audit of 2015 Financial Statements, the Internal Auditors' Reports for 2015 and the Internal Audit Schedule for 2016 and 2017. The committee had also reviewed the annual Procurement Report for 2016 and the Management Accounts for December 2015 and January 2016 in addition to meeting with the Internal Auditor.

7 Scientific Advisory Committees

The Authority discussed the future structure of the scientific advisory committees. It was agreed that the HPRA set up a subgroup to consider the matter in more detail.

8 Advisory Committee for Veterinary Medicines (ACVM) – 2 March 2016

The Chair provided an overview of the highlights of the meeting which included welcoming new and returning members, a peer review of a HPRA product assessment, pending referrals to the CVMP and the publication of the HPRA Report on Antimicrobial Resistance. An overview of manufacturing issues in India and China, recent licensing tables and updates from EU meetings were also presented to the Committee. In addition, the Chair's Report for the meeting was noted by the members.

9 Medicine Shortages

The Authority was provided with an overview of the HPRA response to the Department of Health proposal that the HPRA take a role in co-ordinating a national approach for management of medicines shortages. The HPRA was prepared to undertake such a role but it was noted that staff and resources would have to be approved by the Department.

10 Authority Calendar

The Secretary was requested to circulate the above document for review. The document will be included as an appendix to the Authority meeting pack in future.

11 Draft Code of Practice Governance of State Bodies 2015

The Secretary was requested to circulate this document for review.

12 Eolas

An overview of the Eolas project to date was provided. The Authority was reminded that this is a very significant IT project for the organisation and is quite complex given it spans the four scientific departments. The benefits will be that the seven current workflow/database systems in the organisation will become fully consolidated under one standard system with one software maintenance fee per annum. It was proposed that regular updates be provided to the Authority in relation to the progress of the project.

13 Status Report: HPRA Strategic Plan 2011-2015

The Authority noted the above.

14 Zambia Project

An overview of the project was provided by a senior clinical assessor who spent two weeks in Zambia, advising the Zambian regulator (ZAMRA) as part of the three year HPRA project with the PM Group. The Authority was complimentary of the work to date and the developmental opportunities for staff and for the organisation. It may also be possible for senior staff from ZAMRA to visit the HPRA under the terms of the project. Consideration is also being given to sending a senior inspector to ZAMRA for six months to aid with the project.

15 Market Research

It was noted that Behaviour and Attitudes, on behalf of the HPRA, has carried out the third nationally representative survey of Irish adults. The research involved face to face interviews with 1,000 adults aged 16+. Previous studies were carried out in 2010 and 2012.

The goal of the survey is to explore consumer knowledge of and attitudes towards a range of issues relating to general health with a specific focus on human medicines. The results from the survey will assist in the development of the HPRA public information and advertising campaign planned for 2016. The brand awareness results in particular will be used as a baseline to track future awareness levels.

16 Financial

The management accounts for December 2015 and January 2016 were noted by the members.

17 Licensing Activities

The tables of licences approved by the Management Committee during the period 22/01/16 to the 11/03/16 were noted by the Authority.

18 Authority Meeting Dates 2016

The Authority noted the meeting dates for 2016.