HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

11 May 2016

Authority Meeting Report

1 Declarations of Interest

There were no conflicts of interest declared.

2 Health and Safety

It was noted that the HPRA successfully passed the Health and Safety Authority inspection of 21 April.

The findings were satisfactory with a number of recommendations for improvement. Most of the recommendations were minor and related to updating of documentation. The Safety Officer and Secretary to the Authority was complimented on the outcome and work to date. The support of staff from all departments who had assisted in preparing for the audit was acknowledged.

3 Risk Management

The Risk Register was reviewed in detail by the Audit Committee at its meeting earlier that day. The Chair commended the work on the Risk Register to date as part of a robust process.

4 Chief Executive's Report

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

- The Department of Health is reviewing the HPRA proposal in relation to taking a role on managing medicines shortages in Ireland.
- Training materials have been developed to support users of the registration system for emergency medicines which the HPRA has developed.
- The HPRA scientific advice pilot commenced in April.
- In respect of the development project for medicines regulation in Zambia, two HPRA short term technical advisors (STTAs) have both spent two weeks training medicines regulatory staff in Zambian medicines agency (ZAMRA). This was very positively received and highlighted further areas for development in Zambia. There is a possibility that a HPRA staff member may be seconded to ZAMRA for a six month period. The Director of ZAMRA has also been invited to visit the HPRA.
- The medical devices legislation recast is progressing at a European level. With regard to the medical devices fees, the industry had been informed that a self-funding model to cover the HPRA costs of regulation in this area was required.
- In the area of public health, a new group of 13 interchangeable substances is to be formally requested by the Minister for Health for inclusion on the interchangeable list based on identified cost savings by the HSE.
- As regards international developments, the HPRA is to meet with its UK counterpart the MHRA in a bilateral meeting at the HPRA on 27 May to discuss issues of mutual interest. There is also a bilateral meeting scheduled with the Chinese FDA in June. The Authority

expressed its support for the HPRA bid to host the WHO ICDRA (International Conference of Drug Regulatory Authorities) in 2018.
- In relation to patient engagement, the HPRA met with the Irish Platform for Patients' Organisations Science and Industry (IPPOSI) in April.

5 Audit Committee Meeting – 11 May 2016

The Authority noted the agenda of the above meeting. The Chair provided a brief overview of the meeting held earlier that day. It was noted that the Committee had reviewed: the Risk Register, the System of Internal Control, the Chairman's Statement for 2015, the reconciliation of the end of year accounts 2015 and the Management Accounts for February and March 2016. The Committee was satisfied to recommend them to the Authority for approval. The draft financial statements were reviewed in detail including the HPRA compliance with FRS102. The Audit Committee also reviewed the SOP on fee setting.

6 Remuneration Committee Composition

It was noted that the former Remuneration Committee to review the performance of the Chief Executive is now called the Performance Review Committee. It was agreed that the Terms of Reference be updated to include the Chair of the Authority as the Chair of the Committee.

7 Review of Use of External Experts

The Authority discussed the future structure of the scientific advisory Committees and the use of external experts. It was agreed that the HPRA set up a subgroup to consider the matter in more detail with a technical lead from the HPRA and subgroups of external experts to include veterinary sciences. The findings are to be brought back to the September meeting of the Authority.

8 Advisory Committee for Medical Devices (ACMD) – 26 April 2016

The Chair of the ACMD provided a brief overview of the highlights of the meeting: welcoming the new committee for a five year term, medical devices vigilance and market surveillance activities, and a status update on the revision of the medical devices legislation.

9 Communications Strategy

An overview of the proposed Communications Strategy was presented to the Authority. It was noted that this is the second HPRA Communications Strategy building on previous strategies in place since 2010. This strategy aligns with the HPRA Strategic Plan 2016-2020 and goal two of that strategy which is to ensure that users of health products are well informed. The Authority adopted the Communications Strategy.

10 International Collaboration

An overview was provided of HPRA participation in international regulatory initiatives. The HPRA currently plays a leading role at a global level as key members of the management committees of the International Medical Device Regulatory Forum (IMDRF) and the International Coalition of Medicines Regulatory Authorities (ICMRA) of which the HPRA is Vice-Chair. It also plays a

significant role at a European level within the scientific and strategic committees of the EMA and the HMA.

It was noted that ICMRA has established projects in relation to good manufacturing practice (GMP) inspections, generic medicines, communications, capacity building and assisting in the monitoring of supply chain integrity. It is currently working on new initiatives aimed at bringing greater collaboration among members in relation to pharmacovigilance, supply chain integrity and emerging public health crises.

As part of the IMDRF, the HPRA has worked on a number of projects including bringing greater harmonisation in the development of standards for patient registries, development of guidance on medical device software and medical device standards. The HPRA has also held the international secretariat of the National Competent Authority Report (NCAR) Exchange since 2013 and works as an active member of the working group made up of the EU Commission as Chair, Germany and Spain.

In February 2016, the HMA/EMA published a joint five year strategy for the network responsible for the regulation of medicines in Europe. The HPRA 2016-2020 strategy is closely aligned to the HMA/EMA strategy and includes many of the same strategic objectives.

Within the EMA scientific committees, the HPRA currently holds the Chair of the Committee for Medicinal Products for Veterinary Use (CVMP) and is vice Chair of the Pharmacovigilance Risk Assessment Committee (PRAC). It was also noted that the Pharmaceutical Assessment Manager for veterinary medicines has recently been elected as Chair of the Quality Working Party.

The Authority was complimentary of the breadth of HPRA engagement at international and European levels.

11 Eolas

An overview of the Eolas project to date was provided. The Authority expressed satisfaction with the progress made since the last review.

12 Authority Training Day

The Authority was reminded that there would be a training day focusing on board effectiveness taking place following the next meeting on June 23. Additional training on Corporate Governance is scheduled for September 2016.

13 Financial

The management accounts for February and March 2016 were noted by the members.

The Authority approved the System of Internal Controls, the Chairman's Statement and the Financial Statements as recommended by the Audit Committee.

14 Licensing Activities

The tables of licences approved by the Management Committee during the period 18/03/16 to the 29/04/16 were noted by the Authority.

15 Authority Meeting Dates 2016

The Authority noted the meeting dates for 2016. It was agreed that alternative dates for the September 21 date be circulated to the Authority. However, if all members could not attend on an alternative date then the original date would proceed as planned.