

29 October 2014

Board Meeting Report

1 Declarations of Interest

There were no conflicts of interest declared.

2 International Conference of Drug Regulatory Authorities (ICDRA)

The Chief Executive indicated that should the HPRA host the ICDRA conference on behalf of the WHO in Dublin in 2016 that venues and accommodation are available.

3 Draft Veterinary Legislation

The veterinary legislation proposal from the European Commission was noted by the Authority. The impact of the proposed new legislation is still uncertain and will be reviewed internally.

4 Chief Executive's Report

The Chief Executive provided an overview of the main highlights of his report:

- The HPRA has now taken on the full licensing role for veterinary clinical field trials.
- The Chief Executive has met with the newly appointed Secretary General of the Department of Health.
- There were ongoing negotiations on the environmental impact of medicines and the proposed European legislation in this area.
- In respect of ICT, following a tender process the HPRA is finalising the appointment of a provider for the new workflow solution. In addition, Malta has sought some ICT support from the HPRA.
- The tender documents for the appointment of media advisors have been reviewed and the successful bidder selected. As part of the public communications plan, a selection of HPRA leaflets has been placed in the majority of GP practices.
- The HPRA is to co-host with An Garda Síochána and INTERPOL an international conference in Dublin on the 19th and 20th of November which will review 10 years of INTERPOL involvement in combating pharmaceutical crime.
- The HPRA was placed number six in terms of Pharmacovigilance Risk Assessment Committee (PRAC) rapporteurships awarded to national competent authorities during 2013.
- Council Working Party meetings and discussions on the revised medical devices draft Regulations are ongoing. The HPRA has commenced hosting the Secretariat for the International Medical Devices Regulatory Forum (IMDRF).
- In relation to interchangeable medicines, the 40 active ingredients that the Department of Health and the Health Service Executive have asked the HPRA to process are substantially completed. A number of expressions of interest for switching applications for the first list of 12 active ingredients have been received.

5 Committee Meetings

5.1 Audit Committee – 29 October 2014

The Chairperson welcomed Prof. Keane to the Committee. The Chairperson then provided an overview of the meeting highlights including the draft internal audit plan and the two audit reports presented to the Committee for bank and cash, and payroll, where no issues were noted. The Director of Finance, Corporate and International is to ask the Internal Auditor for input into the future HPRA accounting system. An overview of the purchasing, procurement, credit card and cheques standard operating procedures (SOPs) was provided to the committee. It was also noted that the 2014 financial statements are to be adjusted on a once off basis to comply with International Accounting Standard (IAS) 102, which is applicable from 1 January 2015.

5.2 Advisory Committee Veterinary Medicines – 8 October 2014

The Chairman's Report was noted by the Authority.

6 Financial

The management accounts for August and September 2014 were noted by the members.

7 Licensing activities

The tables of Licences from 12/09/14 to 17/10/14 approved by the Management Committee were noted.