

25 March 2015

## Authority Meeting Report

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

It was noted that the Supreme Court struck down a section of the Misuse of Drugs Act 1977. As a result, the Minister for Health brought forward emergency legislation.

### 4 Chief Executive's Report

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

- A staffing strategy document for 2015 has been submitted to the Department of Health.
- The development of the new a new strategic plan for 2016 to 2020 is progressing. All staff, members of the scientific advisory committees and external stakeholders have been consulted.
- The development of the HPRA EOLAS workflow project continues to progress.
- In relation to Regulatory Science Ireland (RSI), of which the Chief Executive and Prof Caitriona O'Driscoll are Board members, it was noted that the first RSI branded conference on knowledge management is planned for March 26 and 27 in Dublin Castle. It is expected that Minister Varadkar will attend at the close of the first day.
- With regard to medical devices, the joint notified body assessment of the National Standards Authority of Ireland (NSAI) took place in early March at the NSAI offices. The joint assessment team included three members from Europe's Food and Veterinary Office as well as national experts from the UK's MHRA and the Turkish regulatory agency. The HPRA continues to provide support in partnering with other European regulators in the joint assessment programme. A recent example was the HPRA's participation in the assessment of a Danish notified body.
- The HPRA hosted a meeting of the International Medical Device Regulators Forum (IMDRF) subgroup on the Medical Device Single Audit Programme (MDSAP). The weeklong meeting held at the HPRA offices was attended by representatives from Australia, Brazil, Canada, Japan and the United States. Europe was represented by the HPRA, the MHRA, the European Commission and the Food and Veterinary Office. Observers from the Asian Harmonisation Working Party and the World Health Organization (WHO) also attended.
- The CESP IT solution, which the HPRA initially developed and continues to manage and operate, has been adopted as the future agreed registration portal for the EU medicines network. The Authority complimented the Chief Executive and the IT Director on this significant achievement.

## **5 Committee Meetings**

### **5.1 Audit Committee – 25 March 2015**

A verbal update of the meeting held earlier that day was provided by the Chairperson of the Committee. It was noted that the procurement plan for 2015 and the revised internal audit plan had been approved.

### **5.2 Advisory Committee for Veterinary Medicines (ACVM) – 4 March 2015**

The Chairperson of the ACVM provided an overview of the main items discussed which included details of a peer review of a veterinary medicine assessment, pending referrals at the EMA's CVMP and the HPRA's joint scientific advisory committee antimicrobial resistance subgroup. In addition, updates were provided in respect of ACVM nominees, the annual suspected adverse events report and the input required from members in respect of the HPRA's strategic plan for 2016-2020. A discussion also took place on the future skills that will be required by Committee members.

## **6 Strategic Objectives Status Report for 2014**

The Authority noted the progress against plan as outlined in the above report.

## **7 Financial**

The management accounts for December 2014 and January 2015 were noted by the members.

## **8 Licensing Activities**

The tables of licences from 23/01/15 to the 13/03/15 approved by the Management Committee were noted.

## **9 Appointments to the Authority (Board)**

As the terms of office of five HPRA Authority members expire at the end of the year, an outline of the new State Board appointments process was provided. All interested parties are required to register their interest through the Public Appointments Service for final consideration by the relevant Minister.

## **10 Sponsorship of National Concert Hall Music Programmes**

The Authority agreed that the HPRA continue to support the education and outreach projects of the National Concert Hall. The *Health and Harmony* project brings music to those living with dementia in care homes across Ireland while *Music in Mind* brings music participation workshops to mental health centres nationally.