

24 January 2018

## Authority Meeting Report

---

### **1 Declarations of Interest**

There were no interests declared.

### **2 Matter Arising**

#### *RIP Notices*

The deaths of two previous members of the Authority, Dr Kate McGarry RIP (5 January 2018) and Noel O'Donoghue RIP (12 April 2017), were noted. The Chair requested that letters of sympathy be sent to the families of each of the deceased on behalf of the Authority.

#### *Terms of Reference of the HPRA*

The changes as proposed were adopted. As the role of the secretary is now included in the Terms of Reference, the Chair recommended that the secretary should undertake additional training to support her role.

#### *Digital Spend*

At the last meeting of the Authority, the Chief Executive was asked to provide clarification on the quantum of the digital media spend in the previous public media campaign. It was clarified that €20K had been spent in 2017.

#### *Succession Planning*

This matter will be on the agenda for the March 2018 meeting.

### **3 Health and Safety**

The CE advised that there were no significant health and safety matters to report. A minor incident in the building on 7 December, involving a leak caused by a faulty tap, has prompted an update to internal procedures for handling such situations and training for additional staff.

### **4 Risk management**

There were no issues to report.

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

There were no issues to report.

### **6 Chief Executive's Report**

The Chair proposed that the Chief Executive's detailed report should be taken as read and invited questions or comments from the Authority members and the Chief Executive. The following points were discussed in detail:

- Sodium valproate: Work continues in relation to the ongoing EU referral procedure for sodium valproate. Recommendations are expected to be published following the February meeting of the Pharmacovigilance Risk Assessment Committee (PRAC). Further restrictions and risk minimisation measures are likely for use of the impacted medicines. There will be a need for communication and education for both healthcare professionals and patients. In order to ensure a timely implementation of the restrictions and updates to clinical practice, the HPRA intends to host a special meeting of key stakeholders to discuss the measures and actions relevant to each group.
- Vaginal mesh implants: The HPRA and the European network continue to monitor the situation closely. From a regulatory view point, it is considered that the benefit/risk remains positive. The HPRA recently provided input into a report on mesh implants, which has been commissioned by the Department of Health. The report will consider the devices, their regulation and their use in clinical practice. The matter is likely to be discussed in the future by the Oireachtas Health Committee.
- Pensions: The Chief Executive provided a briefing from an important meeting which took place with the Department of Health on 11 January on the subject of HPRA pensions. A background to the pensions issue was presented as well as previous issues raised by the HPRA representatives. The Department asked the HPRA to provide further analysis of the issues outlined. A follow up meeting is planned and while it may take some time to resolve this matter, the Authority was satisfied that appropriate action is being taken.
- Scientific Animal Protection – Freedom of Information: This matter is listed for hearing in the High Court on 1 May 2018 and is set down for two to three days.
- BT Young Scientist Exhibition: The HPRA's involvement in this event was complimented by the Authority.

## **7 Eolas Update**

The current status is that the first phase (wave one) of the EOLAS project for Veterinary Sciences has now been completed and is operational within the department. Continued support is being provided as part of normal ICT operations. The second phase (wave 2) covering the implementation for human medicines, clinical trials and classifications is progressing well and project costs remain within the agreed budget. A new project manager from PWC will take up the position at the start of February 2018.

## **8 Proposal for Interim Review of the Strategic Plan**

A paper setting out a proposed approach for the mid cycle review of the 2016-2020 Strategic Plan was presented. The management committee conducted an analysis of the possible impact of Brexit on the strategic plan in 2017. This was presented to the Authority at the December meeting. It was agreed that a temporary working group, consisting of the Chair and two members of the Authority, will assist in the review of the strategic plan on behalf of the Authority.

## **9 Conflicts of Interest**

The Scientific Affairs Manager provided refresher training on the HPRA's Conflicts of Interest Policy. This included a presentation outlining the legal basis for the policy, a summary of interests to be declared, a summary of how declared interests are managed and the approach taken to related aspects such as gifts and hospitality.

Following a request to simplify Declaration of Interest forms for external experts, the Scientific Affairs Manager highlighted that additional guidance was incorporated in the form this year. The issue would be monitored closely.

The proposed updates to the Conflicts of Interest policy were also presented. One additional amendment was proposed to section 5.1 to reflect appropriate assignment of responsibilities for oversight at director level for financial affairs.

The Chair thanked the Scientific Affairs Manager for his excellent presentation and reiterated the importance of the topic for members of the HPRA Authority.

## **10 Business Case for Additional Building Space**

A paper was presented setting out the advantages and disadvantages of an opportunity to lease one floor of Alexandra House, the adjacent building to Kevin O'Malley House. The issues outlined were discussed and considered in detail by the members. The Authority gave approval for the Chief Executive to continue to take steps to secure the lease, subject to the following:

- (i) The Authority requested that the first step should be engagement with the Department of Health to get its approval to proceed;
- (ii) Options to share office space with other agencies/bodies affiliated to Department of Health should be explored.
- (iii) Further negotiations should take place with the landlord with a view to securing the best possible terms for the HPRA.
- (iv) Finally, prior to proceeding with a lease, the matter should be brought back to the Authority for final approval. If time was of the essence, a special meeting of the Authority could be called to deal with the matter.

## **11 Cannabis for Medical Use Regulation Bill 2016**

A paper outlining developments in cannabis for medical use was presented. This covered the political background, including the above Bill, the HPRA review and the proposed cannabis access programme. A thematic discussion on the topic was led by Authority Member, Professor Keane.

The HPRA may be asked to take on a possible role in relation to a Cannabis Authority once the legislation has been passed. From the analysis and discussion, it is clear that while parts of this role are appropriate to the HPRA other aspects are not. The HPRA will need to discuss the matter with the Department of Health at an early stage and to include the need for resources in these discussions. It was noted that collaboration with other Government departments, such as Agriculture and Justice, may need to be explored as part of the development of a licensing and inspection framework.

## **12 Resourcing Analysis**

The Chief Executive presented a summary of the technical personnel across each of the technical sections with two support departments presented as comparators. The Chief Executive also

highlighted that recruitment is underway for a number of additional technical resources. The Authority supported the approach presented and future plans.

### **13 HPRRA / IPPOSI Patient Education Programme and future Engagement Plans**

The HPRRA's strategic plan 2016-2020 prioritises the development of better informed users. An outline of the HPRRA's involvement in the IPPOSI pilot patient education programme was given. The HPRRA intend to continue to engage with IPPOSI in future projects. The Authority members were invited to consider other ways in which the HPRRA and the members of the Authority could contribute to this important initiative. The members supported continued interaction with IPPOSI.

*Action:* It was decided that members should reflect on this and revert with suggestions.

### **14 Discussion on Preparation for June Away Day Meeting**

Potential topics for discussion at the Authority away day were tabled. These included the following:

- Technical discussion: For example, the product lifecycle and engagement with the regulatory system using a case study. Consider attendance of one to two stakeholders to share their experiences;
- Behavioural dynamics at meetings;
- Outward engagement: How the organisation engages with external stakeholders;
- The value-add of regulators;
- Stakeholder management.

Members agreed that outward engagement / stakeholder management, particularly focused on ensuring an approach that will instil value in the HPRRA's regulatory role, would stimulate productive discussion and provide useful outputs for the Chief Executive and the wider organisation.

### **15 Publication of Authority Report**

The report for 20 September 2017 was agreed for publication, with two minor amendments.

### **16 Committees**

#### *16.1 Performance Review Committee – 24 January 2018*

The Performance Review Committee reported on its recent meeting with the Chief Executive and confirmation of their utmost satisfaction with and support for the Chief Executive.

(There were no updates from other committees since the last reported meetings).

### **17 Finance**

#### *17.1 Management Accounts November 2017*

This item was postponed as the Audit and Risk Committee had not yet had the opportunity to review the accounts.

## **18 Licensing Activities**

The tables of licenses approved by the Management Committee during the period 08/12/2017 to 19/01/2018 were noted by the Authority.

## **19 Authority Meeting Dates 2018**

The next meeting of the Authority is scheduled for Thursday, 22 March 2018 at 2:00 pm. It was agreed the Secretary would send a reminder to all members.