

14 March 2019

## Authority Meeting Report

---

### 1 Declarations of Interest / Conflicts of Interest

There were no interests declared.

### 2 Human Resources and Change Management

The HPRA was awarded the Keep Well Mark in July 2018, demonstrating the organisation's ongoing commitment to improving the health and wellbeing of employees. As a follow on, the HPRA have been shortlisted for two awards at the Keep Well Mark inaugural awards– 'Best in Class: Leadership' and 'Best in Class: Mental Health'. The Authority commended the work done in this area and ongoing commitment to further development.

Post meeting note: The HPRA won the award for Best in Class: Leadership.

### 3 Health and Safety

There were no issues to report.

### 4 Risk Management

The Chair of the Audit and Risk Committee (ARC) recommended the Risk Register to the Authority, following review by the committee. There were some minor changes reflecting the impact of Brexit and Eolas on the business.

### 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 Chief Executive outlined the following key points and invited comments and queries from the members of the Authority. Specific points discussed included:

- An update on the scientific animal protection FOI/OIC case.
- Resources: The resource capacity in the legal section of the Finance, Corporate and International department has been increased in light of the increased workload in this area for 2019.
- Medical devices reorganisation: The reorganisation is progressing and recruitment is ongoing for the new structure. There have been two internal appointees to the positions of Regulatory and Policy Manager, and Clinical Assessment Manager.
- Open Board: Stakeholders have responded to questionnaires and the outcome will be presented at an upcoming Authority meeting.
- An update on the HPRA response to the Oireachtas Committee of Public Accounts regarding pensions was provided.
- The vacancy for the Director of ICT and Business Services was discussed. The Chief Executive noted that the relevant managers are rotating the lead for the department in

the interim, with oversight from the Chief Executive and support from the Director of HR and Change.

## **7 Brexit**

The Chief Executive highlighted a number of key items from the paper, specifically the progress of the medicines supply-chain and criticality assessment, noting the extensive engagement the HPRA has had with manufacturers and suppliers. An update was provided on the regulatory compliance status of human and veterinary medicines authorised by the HPRA in light of Brexit. A discussion followed on the approach the HPRA is intending to take in relation to managing the pathway to regulatory compliance in the event of a no-deal UK exit from the EU.

## **8 Eolas**

An update on Eolas and its implementation was provided to the members.

## **9 Communications**

A presentation was given to the Authority on the HPRA's communications model and how this has evolved over the past number of years. The discussion focused on further opportunities for improving the communications approach, and how these should augment the existing system, which is working well for the HPRA.

The Authority members expressed satisfaction with the progress to date and the general direction proposed.

## **10 Development of the next iteration of the Strategic Plan**

The proposal for the development of the next iteration of the HPRA's strategic plan was presented to the Authority. Members endorsed the proposed approach, which provides for greater input and involvement from the Authority, including participation in workshops with the Management Committee, senior management and other staff.

The Authority will be kept up to date on progress and will have full involvement in the process.

## **11. Review of System of Internal Controls**

The review of the system of internal controls, documented as part of the annual review of the financial statements, was endorsed by the Authority. The Authority noted that the internal auditor's report commended the robust system of internal controls in place.

## **12 Human Products Monitoring (HPM) – Department Update**

Dr Joan Gilvarry presented an overview of the HPM Department. This included changes in the regulatory approach over the past years, and the challenges and opportunities for the future of the department.

The Chair thanked Dr Gilvarry on behalf of the Authority for her 25 years of exceptional service and wished her well for her forthcoming retirement.

### **13 Statutory Review of the Committees**

An update on the progress of the statutory review of the scientific committees was provided to the Authority. The next step of the review involves meetings with the Chairs of the subcommittees (herbal and clinical trials) and the Management Committee to discuss policy surrounding the proposal. The review will be finalised by mid-2019 with a view to sharing the proposal with Department of Health thereafter.

### **14 Committees**

#### *14.1 Audit and Risk Committee – 14/03/19*

The Chair provided an update to the Authority on the meeting.

A representative of the C&AG attended the committee meeting to discuss the management letter for the 2017 audit.

The appointed internal auditors, Mazars, presented an audit of the system of internal controls. The audit found that the system in place provided a high level of assurance in relation to internal controls. The committee was satisfied with the report.

#### *14.2 Advisory Committee Veterinary Medicines (ACVM) – 13/02/19*

The Chair provided a briefing on the main topic discussed which was the requirement to establish a task force to review the method of supply of anti-parasitic veterinary medicinal products. This has been driven by increasing evidence of the emergence of resistance. The structure and membership of the task force and its objectives were outlined. The Authority supported the approach taken which was deemed to be important to animal and public health protection.

#### *14.3 Advisory Committee Medical Devices (ACMD) – 04/03/19*

The Chair of the ACMD provided an update on the Medical Devices department restructure and the ongoing recruitment to meet the requirements of the new structure. An update on the complexities associated with medical devices supply in light of Brexit was also provided.

### **15 Finance**

#### *Management Accounts – December 2018 and January 2019*

The accounts were accepted following formal review by the Audit and Risk Committee at the March meeting. Authority members had no further queries.

### **16 Licensing Activities**

The tables of licenses approved by the Management Committee during the period 25/01/2019 to 08/03/2019 were noted by the Authority.

### **17 Authority Meeting Dates 2019**

The next meeting of the Authority is scheduled for Thursday, 2 May 2019. It was agreed the Secretary would send a reminder to all members.