HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

19 September 2018

Authority Meeting Report

1 Declarations of Interest / Conflicts of Interest

There were no interests declared.

2 Chief Executive's Report

The Chair commended the work of the Deputy Chief Executive and her team in ICDRA preparations and the delivery of a very successful conference. The Chief Executive added that management committee members also facilitated a number of bilateral meetings, a sidebar meeting on medical devices and a tour of the HPRA building over the course of the week. Feedback from regulators has been very positive. At a recent meeting, positive feedback was received from FDA, EMA and Japanese colleagues. It was noted that the meeting concluded with important regulatory recommendations, which will support convergence, transparency and improved utilisation of WHO systems globally.

The Chief Executive confirmed that the outcomes of the Scally Report would be considered as part of the HPRA crisis preparedness.

An update was provided on the topic of vaginal meshes. This continues to be an area of focus for the HPRA.

The Chief Executive also provided an update on the recall situation concerning valsartan and other sartan-containing medicines. She outlined that a second impurity had been identified and this may lead to further recalls. The situation is under review at national and EU level.

3 Outcome of Authority Strategic Meeting with Management Committee- June 2018

The actions arising from the meeting will be incorporated into the HPRA's business planning processes. This includes regular progress reporting to the Authority.

4 Eolas – Analysis of Impacts

The Director of ICT and Business Services presented on the Eolas project to date, focusing on the analysis and development stages. The Authority commended all involved on the work thus far.

5 Review of Service Plan – Q2 Progress Report

The Director of Quality, Scientific Affairs and Communications noted that the plan has progressed as expected with no areas for concern. The Chair commended the Human Resources and Change team on the work completed to date, the involvement of all team members and noted that results from this are visible through change management project outcomes.

6 Key Objectives and Priorities for 2019

The key objectives and priorities for 2019 were presented to the Authority

Areas of focus include: Brexit; Establishment of an operational shortages unit; Further communications and engagement initiatives; Change management programme for medical devices; Development of an ICT strategy 2020-2026, taking into consideration environmental analysis and EU developments; and Operational performance and monitoring.

7 IBTS Annual Report

The Director of Compliance gave an overview of the 21st IBTS annual report, which had been presented to the Authority. The annual report was adopted.

8 Introduction to New Director of HPAR

The new Director of Human Products Authorisation and Registration (HPAR) presented to the Authority on her background, her vision and her experience within the organisation over the past ten weeks. The Chair and members of the Authority welcomed the new Director and offered support as and when required.

9 Proposed Meeting Schedule for 2019

The dates were agreed.

10 Succession Planning

The Chair provided a verbal update on Authority succession planning.

11 Authority Member Recruitment

A role profile for the vacant Authority position will be sent to the Department of Health. The position will be advertised through PAS in due course.

12 Supplemental Mandate for Signature

The supplemental mandate to add the new Director of HPAR to the approved list of signatories was signed by the Chair.

13 Committees

13.1 Audit and Risk Committee – 19/09/18

An update on the meeting held earlier in the day was provided. The Committee met with the internal auditor, Mazars, and discussed the audit plan for the next two-year cycle.

The risk register updates were reviewed. The risk factor for Brexit had increased from the previous review. One new risk was added in relation the to the veterinary medicines Irish language case. This is considered a medium risk. Two SOPs were reviewed, covering treasury management and electronic banking.

A discussion on the HPRA's 2019 fee proposal took place. It was noted that a general increase of 8% and other increases were proposed due to matters such as increased payroll and pensions costs. Other than a cost of living increase last year, it was noted that there have been no fee increases since 2010 and fee decreases in 2011 and 2012. The Authority agreed the proposal and that the details, incorporating a full explanation for the proposed increases, would be subject to a public consultation.

13.2 Advisory Committee Veterinary Medicines (ACVM) – Extraordinary Meeting – 17/09/18

An update on the extraordinary meeting of the ACVM was provided where a suspension based on a recommendation of the EMA's Committee for Medicinal Products for Veterinary Use (CVMP) was discussed.

13.3 Scientific Committees Review

An update was provided on the ongoing review of the scientific committees.

14 Finance

Management Accounts – July 2018

The Audit and Risk Committee had reviewed and noted the accounts. There were no additional comments.

15 Licensing Activities

The tables of licenses approved by the Management Committee during the period 15/06/2018 to 14/09/2018 were noted by the Authority.

16 Authority Meeting Dates 2018

The next meeting of the Authority is scheduled for Thursday, 6 December at 3:00 pm. It was agreed the Secretary would send a reminder to all members.