HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

20 September 2017

Authority Meeting Report

1 Declarations of Interest / Conflicts of Interest

There were no interests declared.

2 Health and Safety

There were no issues to report.

3 Risk management

There were no issues to report.

4 HPRA Updates (Such as changes to legislation, competencies, and terms of reference)

Refresher training on the HPRA Conflict of Interest policy was provided.

5 Chief Executive's Report

The Chief Executive provided an update on the sodium valproate public hearing at the European Medicines Agency (EMA), scheduled for 26 September. This latest review began in March 2017 and the EMA's safety committee, the Pharmacovigilance Risk Assessment Committee (PRAC), felt it was essential to take into account the views and experiences of patients, affected families and the wider EU public. It therefore decided to conduct a public hearing. This is a new process which allows for greater transparency. The Authority were advised that the hearing would be broadcast live on the EMA's website while a recording of the event would also be subsequently available online.

The Chief Executive also provided background information on the 2018 fee review. The Authority members agreed to the strategy. Consultations have taken place with industry and the outcome will be forwarded to the Minister for Health.

The HPV vaccine was discussed and it was noted that staff are continuing to address media queries, Freedom of Information requests and Parliamentary Questions. The Irish language case (veterinary medicines), where the Department of Agriculture, Food and the Marine and not the HPRA is the defendant, was also noted. As the HPRA believes the case has the potential to significantly impact availability and/or costs of veterinary medicines, the HPRA will assist the Department in defending the case.

An update was also provided in respect of cannabis for medical use. The HPRA's role is now limited to technical representation on the Expert Reference Group and the provision of secretariat support to that group.

The HPRA's audit and follow up actions under the Joint Audit Programme (JAP) have been completed. The next step is for the US to list the HPRA as an equivalent inspectorate under the EU/US mutual recognition agreement.

In respect of strategic planning, there will be a full review of the strategic plan mid cycle in 2018. The Chair reported that there had been a positive recent meeting with the Assistant Secretary and Principal Officer of the Medicines, Controlled Drugs and Pharmacy Legislation Unit of the Department of Health. It was noted that a review of the scientific committees is ongoing, with the participation of the Chairs of the committees and relevant experts within the organisation.

Updates eere also provided on organisational development, which is being co-ordinated through the Human Resource and Change team, and the HPRA Graduate Programme which had launched recently.

6 Medical Devices

A review of the organisational structure for medical devices was discussed in light of the additional requirements arising from the new EU Regulations. An update was also provided on medical device fees which were introduced in 2017 for the first time.

7 Brexit Update

A paper was presented detailing a number of items of interest in relation to Brexit including the public stakeholder event which forms part of the HPRA's Brexit communications strategy. The HPRA was the first agency in Europe to host such an event. There has been considerable feedback from stakeholders and follow up regarding future work. A similar event is planned for 2018.

In light of the potential relocation of the EMA to Dublin, the requirement for more technical staff and new expertise was raised. The Chief Executive clarified that mapping exercises have been completed in-house to determine future requirements for a post-Brexit network and a scenario where the EMA relocates to Dublin. There are huge opportunities and the HPRA is well positioned to react and adapt to the changing environment.

The risk to medicines' availability was also raised. A stakeholder survey has been circulated to marketing authorisation holders (MAHs). Follow-up with MAH's of critical products is part of the Brexit strategy.

8 Eolas Update

An update on Eolas was provided. The next three areas to be developed are human medicines, clinical trials and classifications. These parts of the system are due to be rolled out to the organisation in 2018.

9 Service Plan Update

A detailed report summarising the progress against this years' service plan up to the end of Q2 was presented. Overall, the organisation is on target.

10 HPRA Authority Performance – Feedback from the Institute of Public Administration

Overall, the review was very positive with a number of minor recommendations.

11 Licensing Activities

The tables of licenses approved by the Management Committee during the period 05/05/2017 to 15/09/2017 were noted by the Authority.

12 Authority Meeting Dates 2017

The next meeting of the Authority is scheduled for Thursday, 7 December 2017 at 15:00.