

12 September 2019

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)

There were no updates to report.

5 Chief Executive's Report

The Chief Executive highlighted a number of topics and invited comments and queries from the members of the Authority. Specific points discussed included:

- BIA ALCL: The Chief Executive provided an update on this matter and noted the HSE's plan to outreach to all patients having received breast implants in the past 10 years to highlight BIA ALCL and provide advice.
- Vaginal mesh: This continues to be an area of high focus.
- Pandemrix: The HPRA complied with a court order on discovery of documents on 19 July in relation to the 'lead' case (one of 60 cases), which is set down for a ten-week hearing commencing on 8 October 2019.
- Medical device legislation: An update on the implementation of the new legislative framework at EU level was discussed.
- Zero Gains: The Zero Gains campaign has been relaunched, extending to Facebook and existing social media channels, and using geo-targeting. Two high profile posters are on Westmoreland Street and in Dundrum shopping centre.
- HPM Director: The recruitment process has started with the aim to appoint a new Director in Q1 2020.

The Chair requested the Director of Finance, Corporate Affairs and International to join the next meeting of the Authority to provide an update of work in that department.

The Chair commended the HPAR team on their contribution to the centralised assessments at EMA level and the significant growth over the year.

6 Brexit

The cross-organisational approach to Brexit preparedness planning co-ordinated by Deputy Chief Executive is ongoing. The momentum since the April deadline has been maintained. Industry has continued to actively prepare through making the necessary regulatory compliance changes as evidenced in the statistics within the paper.

Concerns remain in relation to medical device certificates as not all have transferred to an EU 27 notified body.

The government wide approach continues, with weekly meetings with the Secretary General, operations and communications colleagues. The HPRA attended two stakeholder events, focused on briefing representatives from the health care professions and industry representatives on Brexit planning at government level.

The Chair commended the Agency staff involved in the significant amount of work to date.

7 Building

An update was provided on the new floor in Alex House.

8 Eolas

The ICT team members presented on the current status of the Eolas project, the approach taken and controls in place to prepare for the future of the system. The system has now moved out of the development phase to a maintenance phase.

9 2020 Proposed Meeting Dates

The dates will be recirculated after the meeting to identify the most suitable dates for all members.

10 Review of the Statutory Committees

An update on the progress was provided since the last meeting.

Two surveys were completed with the Authority and Management Committee and five workshops were held with HPRA staff. A qualitative and quantitative review of the committees was included in the final report. The report included options for change of the committees and enhancing processes for engaging experts, including statutory implications and strategic recommendations.

The Chair thanked the Authority members for their work and requested the Chief Executive share an action plan outlining the next steps for discussion with the Authority in early 2020.

11 Authority Away Day

An update on the away day to develop the next strategic plan was provided. The next steps will involve a meeting of the Strategy Sub-Group (Ann Horan, Dr Diarmiud Quinlan and David Holohan) to reflect on the organisational vision, mission and values to report back to the Authority early in the new year.

12 Succession Planning

An update on the Authority succession planning was provided. Those assigned ownership of particular items should liaise with the secretary for additional support as needed.

13 Service Plan Quarterly Report

The service plan quarterly report was presented. It was noted that while there have been some impacts in light of Brexit, these do not have a material impact on the achievement of the plan.

14 Review of key objectives and priorities for 2020

The document was taken as read. Some key points included:

- A panel of patients/ public representatives will be created to inform the strategy development and website enhancement.
- A digital media strategy is planned and external advice will be sought to inform the approach.
- With regard to the ICT strategy, it was noted that the roadmap has been started and this is key to the sustainability and support of the wider organisation.

15 Authority Performance Evaluation

The outcome of the evaluation was considered to be positive.

16 Terms of Reference (for review)

The Authority proposed a number of changes. The updated version will be brought to the attention of the Authority once finalised.

17 Committees

17.1 Audit and Risk Committee – 12/09/19

The Chair of the Committee noted that the investment strategy remains unchanged.

The management accounts were recommended to the Authority.

17.2 Advisory Committee Human Medicines (ACHM) – 12/09/19

A brief update was provided on the following topics:

- Pregabalin / gabapentin misuse
- Codeine
- FMT programme
- Interchangeability (ongoing work)
- Clinical Trials and licensing
- Brexit and preparedness
- Nominations for membership of the ACHM

The next meeting will take place on 10 December.

18 Finance

Management Accounts – July 2019

The accounts were noted.

19 Licensing Activities

The tables of licenses approved by the Management Committee during the period 07/06/2019 to 06/09/2019 were noted by the Authority.

20 Authority Meeting Dates 2019

The next meeting of the Authority is scheduled for Thursday, 5 December 2019. It was agreed the Secretary would send a reminder to all members.