

16 May 2018

Authority Meeting Report

1 Declarations of Interest

There were no interests declared.

2 Matters Arising

The Director of Quality, Scientific Affairs and Communications (QSAC) is requested to provide an update to the Authority on social media updates as part of the routine media circulations.

3 Meeting Minutes

The minutes of 22 March were agreed with minor amendments.

4 Health and Safety

There were no issues to report.

5 Risk Management

There were no issues to report.

6 HPRA Updates (such as changes to legislation, competencies and terms of reference)

There were no issues to report.

7 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*: The Chief Executive confirmed that questions raised during the recent meeting of the Oireachtas Health Committee on 25 April, have been addressed and a response was sent to the Committee Clerk and to the CEO of Epilepsy Ireland. It was clarified that European safety referrals generate harmonised text which is implemented nationally to ensure wording is common across all member states. A compilation of the historic chronology of all the updates to the product information for all impacted products is on-going.
- *Crisis preparedness at the HPRA to respond to public health issues efficiently and effectively*: It was requested that an update be provided on the HPRA approach to crisis management. The Chief Executive outlined that the members of Management Committee have collectively reflected on this and have set about reviewing the effectiveness of the crisis management procedure in the context of a major public health issue. A paper will

be brought to the Authority in September/ December. The Chief Executive also noted that the issue of mandatory open disclosure is considered in new patient safety legislation.

- *Veterinary recall:* Clarification on the Oxytobel recall was requested.
 - Post meeting note: Information available on the [HPRA website](#).
- *Building:* Feedback from the Department of Health is expected in due course. The Chief Executive and members of the corporate affairs team visited the building and will provide an update at the June meeting.
- *Meeting with the Secretary General of the Department of Health:* The feedback from the meeting was very positive, particularly with regard to the technical support provided by the organisation.
- *HPAR Director:* The Chief Executive confirmed that an appointment has been made and the candidate will take up the position on 16 July. There will be an opportunity to meet with the new Director at the September meeting of the Authority.

8 Presentation: The Regulator of Tomorrow

The Chief Executive presented to the Authority in preparation for the June away day.

9 Eolas Update

The second phase (wave 2) covering the implementation for human medicines and clinical trials is progressing well. The first round of user acceptance testing of the EOLAS project covering workflow across human medicines has been completed. Go-live is scheduled for July/August, followed by stabilisation. Wave 2.5 covering scientific affairs and classification is under analysis and due for completion in May. Development on these areas will begin in June. Project costs remain within the agreed budget.

10 Communications Update

The Communication and Information Manager presented on the proposed information campaign for 2018. The campaign will focus on the negative health effects of anabolic steroids, using Instagram as a platform. The possibility of jointly running the campaign with partner organisations remains under consideration. The timeline for roll-out is autumn 2018.

The Authority members agreed that this was a new type of campaign for the HPRA, focusing on issue based communications. The visuals differ from previous communications in terms of the strength of message and impact. However, this was considered appropriate in light of the targeted nature of this campaign. Endorsement was given to the campaign and the benefits of its impactful nature highlighted.

- Action: Communications Manager to share a Public Health Wales National Image and Performance Enhancing Drugs survey report.
- Post meeting note: [Link to report](#) provided.

11 Shortages Update

The Director of Quality, Scientific Affairs and Communications (QSAC) and the Senior Assessor within the QSAC department presented on the HPRA's role as part of the national approach to

shortages. The presentation covered the work completed to date including the development of a framework for a multi-stakeholder approach to prevent shortages occurring and also to reduce the impact of shortages on patients by co-ordinating the management of potential or actual shortages as they arise. Future plans were also shared including steps to develop and implement preventative strategies to reduce the likelihood of shortages occurring in the first instance. The Authority commended the work to date and agreed that the multi-stakeholder approach co-ordinated by the HPRA is an area of key strategic importance to the organisation and to patients.

12 Succession Planning Update

The Chair advised that work was progressing on this topic and a meeting is scheduled with the Director of Human Resources and Change in the coming weeks. The Authority will be updated later in the year.

13 Mid-term Review of the Strategic Plan: Authority Review

The Chair advised of progress on this topic. One meeting has taken place with participating Authority and Management Committee members. A second meeting is scheduled at the end of May to summarise the findings of the first meeting and to finalise the Authority members' recommendations. Next steps will be shared with the Authority once finalised.

14 Preparations for June Meeting

Details for the away day will be circulated with the Authority meeting papers on 7 June. Members were reminded to reflect on the content of the [Regulator of Tomorrow paper](#) in advance of the meeting.

15 Publication of Authority Report

The Authority report will be reviewed in detail at the June meeting.

16 Committees

16.1 Audit and Risk Committee – 16 May 2018

The Chair of the committee provided an update to the Authority. This covered the year-end financial statements, BDO internal audit feedback on GDPR and IT operations audits conducted in Q1 2018, and the draft audit plan of the newly appointed internal auditor, Mazaars.

16.2 Advisory Committee Veterinary Medicines (ACVM)

No update since the last meeting.

16.3 Advisory Committee Medical Devices (ACMD)

No update since the last meeting.

16.4 Advisory Committee Human Medicines (ACHM)

The Chair of the ACHM was not in attendance. The document circulated was taken as read.

16.5 Statutory Review of Scientific Committees

The Chair of the ACMD provided an update on the work to date. The questionnaires have been circulated to Authority and Management Committee members. Questionnaires will be circulated to committee and subcommittee members in the week ahead. The next steps include agreement of the workshop teams. Meetings with Chairs of the committees will be scheduled for later in the year. Compilation of a report is in progress and will be shared once finalised.

17 Finance

17.1 Management Accounts March 2018

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

17.2 2017 Year-end Financial Statements and Accounting Policies

The Deputy Chief Executive, in her capacity of director with responsibility for finance, provided an overview of the financial statements and accounts. The financial statements for the year ended 31 December 2017 were presented in detail to the Audit and Risk Committee. The committee's attention was drawn to the responsibility of the Authority members for the financial statements. The financial statements were reviewed and approved by the Authority.

17.3 Reconciliation of Accounts

The reconciliation of the financial statements to the December management accounts was reviewed and approved by the Authority.

17.4 Corporate Procurement Plan 2018

The corporate procurement plan 2018 was reviewed and approved by the Authority.

18 Chairman's Statement to the Minister on the Code of Governance for State Bodies

The Chairman's Statement to the Minister on the Code of Governance for State Bodies was reviewed and approved by the Authority.

19 Licensing Activities

The tables of licenses approved by the Management Committee during the period 16/03/18 to 11/05/18 were noted by the Authority.

20 Authority Meeting Dates 2018

The next meeting of the Authority is scheduled for Thursday, 14 June at 9:00 am in the River Lee Hotel, Cork. It was agreed the Secretary would send a reminder to all members.