

2 May 2019

Authority Meeting Report

1 Declarations of Interest / Conflicts of Interest

There were no interests declared.

2 New Authority Member

Dr Keane agreed to act as mentor to the newly appointed Authority member, Prof David Kerins.

3 Health and Safety

The Chief Executive provided an update on two protests held by the National Animal Rights Association (NARA) outside the HPRA offices in recent weeks.

4 Risk Management

There were no issues to report.

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

There were no updates to report.

6 Chief Executive's Report

The Chief Executive provided a briefing on the following matters: transvaginal mesh; breast implants and BIA-ALCL; valproate; cannabis; and the Children and Family Act as it relates to assisted reproduction.

It was noted that a consultancy contract for an Interim IT Manager has been circulated through the government procurement office tendering process which the Authority approved.

7 Eolas

The update report on the Eolas project was discussed.

8 Authority Calendar 2019

The calendar is up to date. The Chair will meet with the Secretary to update the structure.

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

9 GDPR Update

The Director of Quality, Scientific Affairs and Communications joined the meeting.

A report was presented to the Authority on the legislation and regulation associated with general data protection, how the new regulation impacts on the HPRA and progress on its implementation.

10 Strategic Plan 2018 Progress Report and Summary

A comprehensive update on the progress of the organisation's current strategic plan was presented. Delays on progress in small number of areas and the reasons for these were noted and accepted by the Authority.

11 Next iteration of the Strategic Plan

The Chair noted the importance of the Authority and Management Committee in jointly developing the strategic plan, through participation and co-decision making through the various stages of the process.

The research phase will include a targeted approach to engaging and consultation with stakeholders. It was agreed that external review and validation would be a key component of the development, early in the process and prior to agreeing the final strategic areas. The mission, values and vision of the organisation should also be considered early in the process.

The strategic meeting of the Authority and Management Committee on 6 June will focus on this topic in more detail.

12 Service Plan Quarterly Report - Q4 2018

The outturn of the Service Plan for 2018 was presented to the Authority. Over 70% of actions were completed. In relation to outstanding actions, there are no issues of concern and the majority relate to issues where the HPRA are reliant on inputs from external parties such as, for example, development of legislation.

The Authority noted that the significant workload associated with Brexit did not present a challenge to business as usual, and the majority of tasks were executed as planned.

13 Veterinary Sciences Department

The work of the Veterinary Sciences Department, including challenges and opportunities, was presented to the Authority. A discussion followed on the changing regulatory environment for regulation of veterinary medicines. Other key public health challenges, including tackling antimicrobial resistance, were discussed.

14 Brexit

The Chief Executive provided an update on Brexit. It was reiterated that the whole of Government approach would continue. It is imperative that the momentum is not lost over the next five months prior to the October deadline. The dynamic of the market will change in the context of criticality and dependency on medicines and devices, and availability. Industry will be requested again to maintain its progress on preparing for a hard Brexit. The HPRA remains

committed to ensuring, to the extent of our competencies, continued supply of medicines and medical devices.

15 Authority/ Management Committee Strategic Meeting June 2019

The Chair provided an update on the structure of the day. There will be an opening presentation by a speaker, to be confirmed by the Chief Executive. The first breakout session will be on the topic of the next strategic plan and will include participation by the Authority and Management Committee. The second session will focus on succession planning and will be attended by the Authority members only. The meeting is scheduled to take place on 6 June.

16 Statutory Review of the Committees

An update on the progress since the last meeting was provided. The analysis of the workshops and review of follow up comments has been completed. The primary topic of discussion was the register of experts: how this can be coordinated, how communication can be optimised and how greater inclusion can be achieved. A report is being drafted and will be presented at the June meeting.

17 Audit and Risk Committee (ARC) – 2 May

The Chair provided an update to the Authority on the meeting. The Chair noted that the ARC had reviewed the financial statements, the reconciliation of the management accounts to the financial statements and the report of the Chairperson. The ARC also reviewed the HPRA's procedure for protected disclosures and Code of Conduct.

18 Financial Statements

The Financial Statements for the year ended 31 December 2018 were presented in detail to the Authority. The Authority also reviewed the reconciliation between the management accounts and the financial statements. It was noted that the external auditor, DHKN, on behalf of the C&AG, had completed the audit and expressed a preliminary satisfaction with the financial statements. The Authority approved the financial statements subject to any change that the C&AG may have.

The statement of the Authority's Chairperson to the Minister on compliance with the Code of Practice for the Governance of State Bodies was noted by the Authority and approved and signed by the Chairperson.

19 Management Accounts – February 2019

The management accounts were noted.

20 Licensing Activities

The tables of licenses approved by the Management Committee during the period 15/03/2019 to 26/04/2019 were noted by the Authority.

21 Authority Meeting Dates 2019

The next meeting of the Authority is scheduled for Thursday, 6 June 2019. It was agreed the Secretary would send a reminder to all members.