

6 June 2019

Authority Meeting Report

1 Declarations of Interest / Conflicts of Interest

There were no interests declared.

2 Reappointed / New Authority Members

The Chair congratulated Prof Elizabeth Keane and Dr Diarmuid Quinlan on their reappointment to the Authority for a second term and welcomed Prof David Kerins who was attending his first meeting. Each of the Authority members introduced themselves in turn and welcomed the new member.

3 Health and Safety

There were no issues to report.

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 issues to report.

6 Chief Executive's Report

The Chief Executive presented on key points and invited comments and queries from the members of the Authority. Specific points discussed included:

- Cannabis for medical use: The Minister for Health is due to sign the legislation that will underpin the Medical Cannabis Access Programme in the coming weeks. The HPRA provided input into the drafting of the legislation. The Minister will have the responsibility to list products available under the programme in a Schedule to the Statutory Instrument. Updating of the Schedule will be an iterative process in line with applications made by companies to have products included in the programme that are considered to meet required criteria.
- See Change: The HPRA signed the See Change pledge on 23 May to become a See Change workplace partner. Colleagues have been working with See Change since May 2018 and have progressed through the 'Six Step Pledge Programme' to bring the HPRA to a point where it is now a partner organisation. This will involve ongoing collaboration with See Change in the area of mental health wellbeing to provide better outcomes for all in the HPRA.
- Vaginal mesh: The HPRA continue to engage with the clinical community on this topic.
- Pandemrix: An update was provided on the preparations for the upcoming court case.

7 Eolas

The Chief Executive provided an update on the Eolas project. A revised governance approach with input spread across the ICT and Business Services team has been working well. An interim senior IT manager will start in the next week to replace the ICT and Business Services Director.

8 Board Calendar 2019

The structure of the calendar was updated following the May meeting.

9 Statutory Review of the Committees

The Chairs of the advisory committees for human and veterinary medicines provided an update on the progress since the last meeting. The existing committee arrangements were examined, at national, European and international level. This included bodies under the aegis of the Irish Department of Health, the European Commission and EMA scientific committees. Other EU national competent authorities were also considered.

Two surveys were completed with the Authority and Management Committee and five workshops were held with HPRA staff. The HPRA scientific committees were reviewed in a qualitative and quantitative manner and information will be included in the final report. The report will include options for change of the committees and enhancing processes for engaging experts. It will also include statutory implications and strategic recommendations. The report will be presented at the September meeting of the Authority.

10 External Attendees at Authority (Board) Meetings

It was agreed that a well-defined procedure would be developed to allow external attendees attend one to two Authority meetings per annum. This will be particularly positive from a transparency and stakeholder engagement viewpoint. It was agreed that a pilot with other health sector partners and HPRA staff could be rolled out to test the model, once defined.

11 Performance Review Committee – 5 June

The Performance Review Committee met with the Chief Executive on 4 June to review her goals for 2019 and to discuss progress thus far. The Committee expressed satisfaction with the Chief Executive's performance to date.

12 Management Accounts: April 2019

The management accounts were noted.

13 Licensing Activities

The tables of licenses approved by the Management Committee during the period 03/05/2019 to 31/05/2019 were noted by the Authority.

14 Authority Meeting Dates 2019

The next meeting of the Authority is scheduled for Thursday, 12 September 2019. It was agreed the Secretary would send a reminder to all members.