

7 May 2020

Authority Meeting Report

1 Declarations of Interest / Conflicts of Interest

None noted.

2 Engagement Survey

It was noted that the HR Engagement Survey results would be circulated to the members. A presentation of survey analysis and trends by the Director of Human Resources and Change (HRC) will be tentatively scheduled for September meeting.

3 Health and Safety

COVID-19 Update and Building Closure

It was noted that the HPRA building has been closed since mid-March. This is in line with Government guidelines to ensure the health and safety of staff. A very limited number of staff are accessing the building by exception where this is considered critical to the business or the office facilities. The majority of staff are working remotely, due to the collaborative efforts between several HPRA departments and in particular IT colleagues. There have been a number of communications to staff on COVID-19 and appropriate hygiene behaviours. Considerations have begun on the arrangements that will be necessary to provide for a safe return to the workplace in line with the phased Government approach. Based on current plans, this can commence from early August.

4 Risk Management

There were no issues to report.

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

A number of changes to legislation due to COVID-19, were highlighted. These were addressed in the Chief Executive's report.

6 Chief Executive's Report

The report was taken as read. The Chair asked the Chief Executive to highlight key points and invited comments and queries from the members. Among the specific points discussed were a number of public health issues including:

- On-going regulatory review of vaginal mesh products: A brief overview of likely next steps was provided.
- An update was given to the Authority on regulatory developments and national activities regarding sodium valproate, including the preparation of a special edition of the drug safety newsletter, focusing on the on sodium valproate and the pregnancy prevention program.

- Magec System spinal correction rods: These devices are the subject of a market surveillance review by the medical devices team, in conjunction with the MHRA in the UK, following the issuing of a field safety notice by the manufacturer in April 2020, which paused the supply of products pending the review. The HPRA continues to engage with the manufacturer in relation to this review and will continue to work with the MHRA to share information regarding concerns over the technical documentation and concerns identified from reviewing the results of the explant analyses. Engagement with implanting surgeons is also continuing.
- Brexit preparations will be stepped up in the coming weeks. The internal Brexit group has recommenced regular meetings, and engagement with industry on completion of final preparations in advance of the year-end timeline has begun. The potential impact of the Northern Ireland Protocol in terms of its implications for pharmaceuticals and medical devices is an issue to be resolved before year-end (though largely for the UK and European Commission to determine).

7 ICT Digital Transformation Presentation

The Senior ICT Manager joined the meeting to provide an update on the approach to the Digital Transformation Strategy in line with a presentation circulated to the Authority.

The Chair and members expressed their thanks to the ICT department for their work in facilitating remote working for staff during COVID-19, which reached 335 users by April 2020.

It was noted that appointment of a Director of ICT and Business Services was scheduled for mid-2020. This was deferred in light of developments with COVID-19. However, given the likely prevalence of the current situation over the next months, the aim is to initiate recruitment in May/June.

8 Development of the next Strategic Plan (2021 – 2025)

The Chief Executive provided an update on the ongoing development of the next iteration of the Strategic Plan, with some amendments to timelines in light of COVID-19. It is intended to complete the plan by year-end as originally projected. A delay of a number of weeks in progress is unavoidable due to the focus on the pandemic. Notwithstanding this, a detailed presentation and thematic discussion with the Authority will take place at the next meeting. Work is ongoing to revise the mission, vision and values. A progress report on this will be provided at the next meeting. The next meeting will heavily focus on getting the guidance from the Authority into the determination of goals and focus areas, and the development of the vision.

9 Review of Statutory Committees

In light of COVID-19, this item is on hold (tentative agenda item for 10 September 2020).

10 Away Day Approach

In light of COVID-19, it was proposed to postpone the away day meeting of the Authority.

11 COVID-19 Emergency - HPRA Response

The Chief Executive provided an update on the HPRA response to COVID-19 in line with the detailed paper circulated to the Authority members. This incorporated a number of focus areas for the organisation including: business continuity planning and maintenance of operations; work to ensure the availability of medicines and medical devices critical to patient care; current status with respect to the development of therapeutics and vaccines; contribution to NPHE and frontline response efforts.

Remote working is operating very well. In spite of increased workloads, business as usual has been maintained fully and this reflects huge commitment from staff during the crisis.

The Chair and members expressed their thanks to Chief Executive on a comprehensive report, and highlighted the excellent business continuity efforts of Chief Executive, senior management and all staff.

COVID related clinical trials, including the establishment of the temporary National Research Ethics Committee (NREC) for COVID-19, in collaboration with HRB, the Department of Health and other agencies, were also discussed.

12 Board Evaluation 2020

The Chair provided an update to the members. Board Excellence has been awarded the contract to lead the annual Authority evaluation process. It was agreed that Board Excellence will be invited to present a short introduction to their work at the June meeting. As part of their evaluation work, Board Excellence asked to attend a meeting of the Authority in an observational capacity. It was proposed that they be invited to remain on at the June meeting, following their presentation.

13 Board Succession Planning

The Chairman updated the members on the Public Appointments Service (PAS) assessment process for the selection of a new Authority member to replace Pat Brangan, who retired from the Authority in December 2019.

The Chair reminded the members that the position of HPRA Chair will become available at the end of December.

14 Board Calendar 2020

The calendar was noted.

15 Publication of Authority Report

The report for January 2020 was agreed for publication. As a follow up to these minutes, clarification was requested on two items as follows. Further updates will be given at the next meeting:

Patient Forum: The Chief Executive updated the members on the progression of patient forum, noting that a virtual meeting will take place to progress this project.

Open Authority (Board) Meeting: The Chairman proposed, in light of COVID-19, that the timeline be amended to commence a pilot in December 2020 or January 2021.

16 Committees

16.1 Audit and Risk Committee (ARC) – 7 May 2020

The Chair of the ARC provided an update on the meeting:

- 2019 Year-end Financial Statements: Approved, subject to any changes that the C&AG may have and the statement on the system of internal controls.
- Reconciliation between the December management accounts and the Financial Statements: Noted.
- Chair's Statement to the Minister on the Code of Governance for State Bodies: Agreed and will be sent to the Chair for signing.

17 Finance

17.1 Management Accounts: February and March 2020

The accounts were noted following review by the Audit and Risk Committee at the May meeting.

18 Licensing Activities

The tables of licenses approved by the Management Committee during the period 06/03/2020 to 01/05/2020 were noted by the Authority.

19 Authority Meeting Dates 2020

The next meeting of the Authority is scheduled for 3 June 2020. Secretary to provide a reminder to all members. The meeting will be held virtually, in line with Government social distancing guidelines