

3 March 2020

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.

The CE noted that there have been a number of communications to staff on COVID-19.

3 Risk Management

The Chair of the Audit and Risk Committee provided an update on a number of risk management documents discussed at the Committee meeting.

This included:

- *Risk Register*: There were a number of changes to the risks, which were highlighted in the document.
- System of Internal Controls: A document outlining the system of internal controls was presented and discussed. The controls in place were considered to be appropriate and sufficient.
- Risk Management Framework: The document was noted. No changes have been made.

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

The final version of the Terms of Reference was adopted.

5 Chief Executive's Report

The Chief Executive updated the Authority as follows:

- In relation to COVID-19, an update was given on on-going work to support the
 Department of Health and HSE including participation in the NPHET and efforts to
 ensure continuity of supply for medicines and critical medical devices / diagnostics. An
 overview was also provided on organisational business continuity planning and in
 particular the implementation of remote working arrangements.
- In relation to Brexit, an update was given on arrangements during the transition period, engagement with the Department of Health in relation to discussions on the Northern Ireland Protocol and planning for the period post December 2020.
- An update was provided on the Magec X spinal system device. There has been limited
 use in Ireland. No adverse events have been reported to the HPRA. Patients are subject
 to regular and enhanced levels of review. The situation is being closely monitored.

3 March 2020 1

6 ICT Digital Transformation Presentation

An update on the approach to the Digital Transformation Strategy was provided. Six key themes of the strategy were presented which will be carried out over 3-5 years: These included Enterprise, Transaction Applications, Stakeholder Digital Integration, Data Management & Decision Support, User Productivity, Technology Infrastructure and Enhanced Governance. An update was given on the current position and development required under each theme.

A standalone Digital Communications Strategy is under development between the Quality, Scientific Affairs and Communications (QSAC) and the ICT and Business Services departments. This will incorporate a number of elements including the redesign of the website.

7 HPM Director Presentation

The new Director of Human Products Monitoring (HPM) presented to the Authority on her background, her vision and her experience in the role since her appointment. The Chair and members of the Authority welcomed the new Director and offered support as and when required.

8 HR&C Strategy

The Chief Executive presented the outturn under the current Human Resources and Change strategy (HR&C). The very high level of delivery and quality of the initiatives progressed to date were acknowledged by the Authority members. The leadership of the Director and work of the department were commended.

9 Strategic Plan 2016-2020 - Update

The Director of Quality, Scientific Affairs and Communications (QSAC) provided an update on the current strategy and cumulative progress and outturn to the end of 2019. Most items are on track with no matters for concern. Where the proposed target has not been met, this is mainly due to matters beyond the control of the HPRA, such as delays with legislation and Brexit. The Authority acknowledged the level of achievement to date.

10 Development of Strategic Plan 2021-2025

The QSAC Director provided an update on progress with the development of the next iteration of the strategic plan. The sessions with staff and the Management Committee, in addition to those with the Authority, provided opportunities for engagement and insights into areas of focus for the new strategy. Next steps include further work on the proposed key themes/goals and department-level analysis.

Work on developing the vision, mission and values is continuing with input from the Authority, the Management Committee and colleagues as necessary. Further feedback will be provided at the May meeting.

The established internal processes for cascading from the strategy to business planning were outlined. From the consultation process, key areas of technical interest and capability over the next 5 to 10 years have been identified and these will inform business planning.

3 March 2020 2

11 Service Plan 2019 – Q3

The QSAC Director presented the service plan activity summary report.

12 Review of Statutory Committees

The QSAC Director presented the plan for the next steps of the committee review. The proposal and timelines were considered to be appropriate.

13 Finance

13.1 Management Accounts November 2019

The accounts were noted.

14 Communications Update

The QSAC Director presented on the communications activities for 2020. A number of initiatives are planned. This includes:

- An online safety campaign to create awareness of the risks of buying health products online. This will be a social media campaign with an initial focus on Twitter, with a series of visuals. The date for finalisation is Q2.
- A corporate brand video, which will be approximately 90 seconds in length, providing a
 high level introduction to the HPRA outlining our public health role and how we delivery
 for patients and/or members of the public. This is expected to be finalised in Q2 2020.

15 Board Calendar 2020

The updated calendar was approved.

16 Publication of Authority Report

The report for December 2019 was agreed for publication, with minor edits.

17 Committees

17.1 Audit and Risk Committee (ARC) – 3 March

The Chair of the ARC provided an update on the meeting and recommended the documents listed under item 3 above.

17.2 Advisory Committee Human Medicines (ACHM) – 3 March

The Chair of the ACHM provided an update on the meeting.

18 Licensing Activities

The tables of licenses approved by the Management Committee during the period 24/01/2020 to 28/02/2020 were noted by the Authority.

19 Authority Meeting Dates 2020

The next meeting of the Authority is scheduled for Thursday, 7 May 2020. It was agreed the Secretary would send a reminder to all members.

3 March 2020 3