

23 September 2020 (meeting held remotely)

Authority Meeting Report

1 Declarations of Interest / Conflicts of Interest

None noted.

2 Health and Safety

There were no issues to report.

3 Risk Management

There were no issues to report.

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

Recent updates to the Code of Practice relating to gender equality and diversity and inclusion were noted and will be discussed at the November or December meeting.

5 Chief Executive's Report

The Chairperson asked the Chief Executive to highlight key points and invited comments and queries from the Authority members. Specific points discussed included:

Public Health – Medical Devices

Learnings from the pandemic and in particular the challenges associated with the availability of medical devices were discussed. The Authority considered that the HPRA should continue its efforts at a European level to ensure enhanced cooperation within the network and a successful implementation of the new framework.

Human Medicines – Nitrosamine

The Authority welcomed the approach that had been taken to date by the European network in the investigation of nitrosamine contamination of medicines containing metformin. This has taken into consideration the need to maintain supply and availability. The importance of the Committee for Medicinal Products for Human Use (CHMP), the European Medicines Agency's (EMA) committee responsible for human medicines, in bringing about a balanced approach to such investigations was noted.

HPRA Business – Brexit

The Authority was updated on HPRA's planning for the year-end timeline including further planned engagement with stakeholders to assess levels of Brexit preparedness. The Authority asked if there were plans for the HPRA to host an industry information event in advance of the deadline. The Chief Executive advised that this is one of the items being considered by the HPRA's Brexit Task Force.

Business Continuity – ICT and Business services (ICT&BS)

The Chairperson welcomed the appointment of a new Application Development Manager, and further education supports for ICT&BS team members. It was noted that the daily operation elements of working from home are progressing well for the ICT&BS team. A further update on this was provided under Item 10.

Communications

The Chairperson commended the quality of the work of the Communications team in providing recent internal communications and external communications on COVID-19 and other matters as outlined in the report. She requested that Authority members would be added to the circulation list for the HPRA internal newsletter and complemented the content and design of the communication. An Authority sharepoint/file share service is to be investigated as a means of providing further communications materials to the Authority.

Remote Inspections

Progress in conducting remote inspections and in more agile ways of working was noted.

New Veterinary Medicines Regulation

Good progress is being made on the implementation of the new veterinary legislation. The Authority requested a further update at a future meeting.

Pandemrix Legal Case

It was noted that the HPRA continues to receive discontinuation notices in relation to Pandemrix cases which are ongoing. The Authority thanked the HPRA legal team and colleagues for the significant work on this item.

6 COVID Emergency, HPRA Response, therapeutics and vaccines

The Chief Executive provided an update on the HPRA response to Covid-19. The considerable workload which the organisation will undertake in relation to regulatory support for the roll-out of the vaccination programme, including post market surveillance, was discussed. The Authority concurred that this as a key priority over the coming months.

The Authority noted the HPRA's involvement in the Department of Health's Immunisation Strategy Group.

7 Patient Forum

An update was provided on the inaugural meeting of the Patient Forum, which was held on 8 September 2020. The Authority expressed their support and noted it as an excellent initiative.

The need for the forum to maintain independence from the organisation was discussed. The Chief Executive advised that this is under consideration and agreed that the appointment of an independent chair would assist in this regard. Currently, during the pilot stage, the services of an independent facilitator have been engaged. The Authority members stressed that inclusion is critical and agreed that a fluid model may support this.

The suggestion was made to consider inviting representatives from areas of current and emerging interest to be present at meetings where the agenda may be of interest to them.

8 Independent Medicines and Medical Devices Safety Review

Discussion focused on the paper outlining considerations on the UK's IMMDS report concerning sodium valproate and surgical mesh and its relevance to the Irish context, which had been provided to the Authority. This is considered by HPRA to be of high priority.

The Authority stressed its support for further engagement with affected patients, patient groups and other related parties and highlighted the need to identify what learnings can be taken on board for the health product regulatory system here.

9 Preparation of Digital Transformation Strategy

The draft Digital Transformation Strategy, including an executive summary, strategic objectives, governance and implementation plan were discussed.

The Authority complemented the worked to date and emphasised the importance of considering and balancing both current and longer term priorities. The longer-term considerations on the IT resourcing model for the HPRA were discussed. A key focus of the plan is to include greater use of shared services, while at the same time developing the skills of existing staff to meet strategic objectives and add value to the organisation. The Authority welcomed the focus on governance in the plan and the approach being proposed to manage larger transformation focused projects. The next steps will be for the Authority to review budgets and the final list of key priorities.

10 HPRA Strategic Plan, 2021 to 2015 – Update

An overview was provided on the current developments of the new strategic plan, and the revised vision, mission and values.

- Mission: The Authority were satisfied with the revised statement. It was considered to be clear and meaningful and in line with the previous guidance of the Authority.
- Vision: It was agreed that further work is required and a further workshop of the Strategy subgroup will be held in the coming weeks to progress this.
- Values: It was agreed that these are progressing well and are nearing finalisation.

Strategic plan: The Authority expressed its satisfaction with the latest version of the goals which are still in draft form but are nearing completion. Members suggested further refinement of some of the goal descriptors, and the need to simplify the language to provide greater clarity. Further discussion will take place at the November meeting of the Authority.

Goal 5, on internal capabilities, is still under development and will be presented at the next Authority meeting.

The Authority expressed their thanks to the Director of Quality, Scientific Affairs and Communications for her work to date on this item.

11 Business Planning for 2021

The service plan for 2021 is being developed from two strands of work: (1) the actions agreed for the new strategic plan and (2) the activities not completed in the current year, which will be carried over to 2021. Planning work and will be completed as soon as the strategic plan has been finalised.

12 Service Plan – Quarterly Progress Update Reports

The service plan update was noted by the Authority. The plan is currently operating at 80% of deliverables and in line with target, and is comparable to previous years in terms of the progress reported at this stage of the year.

13 Risk Management – Review of Risk Register

The risk register, including all updates, was reviewed by the Audit and Risk Committee (ARC) at its last meeting on 22 September. Updates include responding to the pandemic and reflect the impact on the organisation of the roll out of vaccines and mass immunisation programmes. An additional risk under COVID-19 includes the transition to full-scale home working, and the impacts on retention and engagement of staff. There were a small number of other changes noted.

14 Update on HR and Change

A presentation was given by the Director of HR and Change on the HR and Change Strategy 2016 – 2020. This was followed by discussion on the success of the current strategy, reflecting on the improvements made since the strategy commenced, and considering areas to focus on in the next period. The Authority noted the considerable work undertaken by the HR and Change department, and extended their thanks to all involved in working through the strategy objectives. Success of the graduate programme was particularly highlighted. It was noted that the Authority are happy to support further investment in HR and Change initiatives, in light of business transformation and remote operating, in the 2021 budget process.

15 Board Succession Planning

The Authority noted the succession planning update, completed by a HR Consultant and the Secretary. The succession planning work will form part of the hand-over from the current Chairperson to the new Chairperson at the end of this year.

16 Review of Authority Meeting Schedule

Upcoming meetings of the Authority were noted. A reminder note will be circulated by the Secretary.

17 Committees

17.1 Audit and Risk Committee (ARC) – 22 September 2020

The ARC met on 22 September 2020. The ARC Chair provided a report of the September meeting. The following items were brought to the attention of the Authority:

ARC Performance Evaluation Self-Assessment

The members of the ARC carried out an internal review of their own performance on 14 August using the guidance document for audit and risk committees included in the Code of Practice for the Governance of State Bodies. The results of the review were positive and the ARC are performing well against the check-list. The ARC Secretary was thanked for his support in facilitating this review.

ARC Review of Terms of Reference

The ARC reviewed the content of MGT-P0013 (Terms of Reference and Rules of Procedure of the Audit and Risk Committee). A small number of amendments were made.

ARC Review of Risk Register

As under item 13 above.

18 Finance

18.1 Management Accounts: June and July 2020

The accounts were noted by the members.

18.2 Outcome of the Financial Statements Audit, 2019

The Authority was given an update on the outcome of the financial statements audit, undertaken by the Office of the Comptroller and Auditor General (C&AG) and discussed by the ARC at its recent meeting. The audit completion memorandum and management letter issued following the 2019 audit were included in the meeting pack for noting. There were no significant findings.

The audit report was issued with an 'except for' qualification in relation to the non-compliance with the requirements of FRS102 in relation to retirement benefit entitlements. It was acknowledged that this treatment is in line with the instructions of the Minister.

The Authority complemented the HPRA finance team on the audit report outcome.

19 Licensing Activities

The tables of licenses approved by the Management Committee during the period 26/06/2020 to 11/09/2020 were noted by the Authority.