

23 January 2020

Authority Meeting Report

1 Declarations of Interest / Conflicts of Interest

There were no interests declared.

2 New Authority Member

The Chair welcomed Prof Reilly who was attending his first meeting. David Holohan will act as peer support to Prof Reilly.

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)

The review of Terms of Reference is nearing completion and will be shared with the Authority once finalised.

6 Authority Changes and Planning

Prof Reilly's appointment was noted. A second appointment to the Authority is expected in the first half of 2020 as a new post will be advertised via the PAS process in the coming weeks.

As part of the Authority's Succession Plan, the Chair will meet with individual members to discuss terms, renewals and future requirements for the Authority.

7 Chief Executive's Report

The Chief Executive provided an update on the following:

- Oireachtas Joint Committee for Health: An update was provided on recent discussions with the Department of Health, and its request that the HPRA join a meeting of the Joint Committee for Health. The Department was invited to the Committee on the topics of vaginal mesh and sodium valproate on 29 January. The meeting has subsequently been postponed in light of the election. No alternative date has been provided at this time.
- Nitrosamines: The Chief Executive provided an update on the current status of the EU review on nitrosamines. An update on the specific investigation into metformin was also provided.
- Remote working: The roll out of the pilot was noted. It is intended that this will inform an analysis of the potential suitability of a more widespread approach to address the requirements of the HPRA.

- Legal Cases: The outcomes in a High Court case and the appeal to the Office of the Information Commissioner were noted. The Authority commended the work of the legal team and others involved.
- Safety Features Implementation: The current situation was discussed and the role of the Irish Medicines Verification Organisation (IMVO) clarified.
- The appointment of the new Director of Human Products Monitoring was noted. It was agreed that she would attend the March meeting.
- The progress on social media was commended and it was agreed that plans for 2020 should be presented at a forthcoming meeting.
- The number of lead assessment roles in the EMA's centralised procedure that were awarded to the HPRA's Human Products Authorisation and Registration team in 2019 were commended, and demonstrate the significant progress in this area.
- The Chief Executive noted that the coronavirus situation is being monitored and colleagues are in close communication with the Department of Health.

8 Annual Secretary General Meeting Update

The Chair and Chief Executive met with the Secretary General of the Department of Health on 12 December. The meeting provided a good opportunity to elaborate on the recent work of the Authority. The discussion also covered the Strategic Plan 2021-2025, Brexit, the performance delivery outturn and legal cases.

The feedback received was very positive, specifically noting the expertise and professionalism across the organisation and the strong working relationship with the Department.

9 ICT Digital Transformation presentation

The acting head of IT joined the meeting for this item to provide an update on the ICT Digital Transformation Plan. This included a status overview of the operations, ongoing and planned projects, and the departmental reorganisation in 2019. Consideration and inputs have been taken from Service and Strategic Plans, Public Service ICT Strategy, related agencies and initiatives. The key themes include: build to share (infrastructure & applications); digital first (process automation & efficiency); data as an asset; enhancing governance; and improving capability.

The areas of focus for 2020 were presented, alongside a three-year roadmap to illustrate the approach to deliver the strategy.

10 Authority Calendar 2020

The format of the Authority Calendar will be updated and circulated to members for review and input in advance of the March meeting. Members were invited to contact the Secretary with any updates or amendments.

11 Presentation on the Compliance Department

The Director of Compliance provided a comprehensive update on the work of the Compliance Department, including current challenges and opportunities. Specific priorities for the section include increasing complexity in the manufacturing sector, growing challenges presented by

globalisation of the pharmaceutical industry, Brexit impact on the market and managing the inspection resources.

12 Service Plan 2020

The Director of Quality, Scientific Affairs and Communications joined the meeting and presented the key issues for the organisation in 2020 and proposed actions to respond to these issues, as outlined in the Service Plan.

It was noted that Brexit remains a major disruption to the external environment, having the potential to bring long-term changes to the areas regulated by the HPRA in Ireland.

The development of the next iteration of the HPRA Strategic Plan is a significant focus for the year ahead. A number of other areas highlighted included implementation of new legislation, internal capabilities and communications.

The Service Plan was adopted by the Authority.

13 Patient Forum

The Director of Quality, Scientific Affairs and Communications presented a proposal on the establishment of a HPRA patient forum with a view to creating a more systematic approach to listening to and involving patients. Initially the forum will be established on a pilot basis to address topics of relevance to patients and in line with the strategic priorities of the organisation. During this phase, participation will be open to graduates of IPPOSI patient training, which draws on a wide spectrum of patient organisations, and representatives of the main disease areas in Ireland (heart disease, respiratory disease, cancer, and diabetes). This may be extended in time.

An independent Chair will be identified and a governance plan will be put in place, including routine reporting to the Management Committee and Authority.

It was highlighted that it will be important to monitor the benefit of the forum to both participants and the organisation.

The approach was approved by the Authority.

14 Strategic Plan - Next Steps

The Authority was updated on the recent progress with the strategic plan development. A strategy subgroup meeting took place to define the framework and guiding principles to review and update the HPRA Vision, Mission and Values. The process will include input from across the organisation, at all levels.

The next step in the development of the Strategic Plan will involve a meeting of the Management Committee and senior managers on 11 February. Authority members will be invited to join this session, which will take the form of a workshop. This meeting will consider the landscape to 2025 and beyond to 2030.

15 Open Authority Meeting

The proposed scheduling, participation and format for the initial pilot meeting was discussed.

16 Finance

16.1 Management Accounts November 2019

The accounts were noted and are due to review by the Audit and Risk Committee at the March meeting.

17 Licensing Activities

The tables of licenses approved by the Management Committee during the period 06/12/2019 to 17/01/2020 were noted by the Authority.

18 Authority Meeting Dates 2020

The next meeting of the Authority is scheduled for Tuesday, 3 March 2020. It was agreed the Secretary would send a reminder to all members.

19 AOB

19.1 Letter of Engagement 2019 – C&AG

The letter of engagement in respect of the 2019 financial audit was received from the C&AG on 21 January. This will be circulated to the Audit and Risk Committee members post meeting.