

10 December 2020, 2:00 pm (meeting held remotely)

Authority Meeting Report

1 Declarations of Interest / Conflicts of Interest

None noted.

2 Terms of Appointment for New Members

Clarification was provided regarding the Code of Practice, and the Annex on Gender Balance, and Diversity and Inclusion, effective from September 2020. The Department of Health had advised that State Board appointee terms may be renewed up to a maximum of 8 years, with effect for new appointees on or after 17 September 2020.

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

None noted.

4 Chief Executive's Report

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

Public Health – Vaccines and Therapeutics Update

As noted in the papers, on 2 December, the MHRA (UK medicines regulator) approved the emergency use of the Pfizer/BioNTech COVID-19 vaccine.

The HPRA is closely observing the implementation plan for the vaccine in the UK, as it is anticipated that Ireland will have a broadly similar implementation plan.

The Authority emphasised the importance of work on vaccine roll-out and communication by the HPRA at this time. An update was given on media engagements completed to date and currently planned. Communication efforts are being coordinated and aligned with the Department of Health.

The HPRA has been invited to join the Government High Level Taskforce on Covid-19 Vaccine Implementation, chaired by Prof Brian MacCraith. The Chairperson welcomed this development.

The current timelines for the EMA's opinion on the Pfizer/BioNTech vaccine were discussed. An opinion/recommendation for approval from the EMA's human medicines committee (CHMP) is likely on 29 December, with authorisation by the European Commission to follow within the next day.

The Chairperson thanked the Chief Executive for the considerable work involved on this critical matter and stressed the Authority's continued support and interest over the coming weeks and months.

Future of work and implications for HPRA

The Authority was updated on the future of working for the HPRA. It was noted that Mercer has been chosen to support the HPRA in conducting an organisational analysis to inform

considerations on future working models and flexible working arrangements in a post pandemic setting. The HPRA is keen to progress thinking beyond the emergency measures currently in place and take a proactive approach to planning and preparing for the correct balance of working flexibilities. The initial part of the analysis involving the Management Committee will take place before year-end, with further work to take place into 2021. The Authority will be kept updated on this item.

Director of ICT&BS

There was a successful outcome to the recent recruitment competition, and a new Director of ICT and Business Services was appointed.

HR&C – Keep Well Mark

The Chairperson congratulated the Human Resources and Change department and the organisation on the recent re-accreditation of the Keep Well Mark.

Communications – Corporate Video

The Authority welcomed the new corporate video, noting it provides a very clear message regarding the role of the HPRA.

5 Digital Transformation Strategy: For Approval

The Authority was briefed on the final digital transformation strategy and associated budget. The Authority supported the budget presented, noting members are happy to review further budgetary considerations if required.

The Authority approved adoption of the digital transformation strategy.

6 Service Plan 2021: For Approval

The Authority discussed the 2021 service plan. The Chairperson noted that the plan is challenging in light of the current pandemic circumstances. The cascade from the new strategic plan goals and objectives is very evident with collaboration and communication activities being strong areas of focus for 2021 service planning. Regarding service volumes, it was suggested to draw up a side-by-side comparison with the previous year for ease of reference.

It was queried if COVID-19 and other public health issues had been factored in to the plan. It was confirmed that this was the case, and the resource implications and needs for both activities have been factored in.

The Authority approved the adoption of the HPRA Service Plan 2021.

7 Strategic Plan 2021 – 2025: Update

Two overview documents were presented covering the plan itself and the HPRA's Mission, Vision and Goals. The Authority was also presented with a draft design version of the strategic plan. Some suggestions were made to improve the design element to better reflect the role of the organisation in protecting animal health and supporting one-health objectives.

The Authority approved the adoption of the final HPRA Strategic Plan 2021 – 2025.

The Authority and Chief Executive thanked the Director Quality, Scientific Affairs and Communications for her considerable work on the strategy over the last two years, and commended her on an excellent final document.

8 Board External Evaluation – Update Presentation

Board Excellence presented on its 2020 board evaluation. The presentation highlighted the evaluation outcome and key recommendations, based on interviews and questionnaires completed by all of the Authority and some members of the Management Committee earlier this year. It was highlighted that the HPRA Authority is considered a high-performing Board.

Proposed next steps included discussion on the draft evaluation findings by the Authority with the Chair to revert with any observations with a view to finalising the report. An action plan will be agreed by the Authority to implement recommendations.

The Chairperson and Chief Executive thanked Board Excellence for the considerable work on the evaluation. It was noted that the recommendations are fair and offer an opportunity for improvement. The outcome of the evaluation was considered positive.

9 Brexit Update

The Deputy Chief Executive provided an update based on the content of the paper provided.

It was noted that the HPRA has been planning for a 'no-deal' Brexit scenario and is prepared for this outcome. The HPRA regularly meets with the Department of Health and HSE to ensure a co-ordinated approach and ensure that any high-level issues are flagged and addressed swiftly. Key priorities include maintaining supply of medicines and medical devices, and engagement with the Commission on areas of concern. All the indications from the work carried out to date suggest that there is sufficient resilience in the medicines and medical device supply chains to ensure sufficient availability of products post 31 December 2020. Stakeholders have provided significant reassurance on their level of preparedness. While the longer term impact of Brexit will be seen over the next number of years, the current emphasis however is ensuring immediate continuity of supply and maintaining sufficient authorisations to supply the market post 31 December. This work is progressing well.

It was noted that there is a robust HPRA communications approach in place. In addition, there is a centrally co-ordinated communications group via the Department to ensure a single co-ordinated message from Government, which includes medicines. At agency level, stakeholder information is available on the HPRA website, and there is provision for communications to wholesalers and pharmacists to help prevent medicine stockpiling.

The Chairperson commended the Deputy Chief Executive and the Brexit team involved in the significant amount of work completed and the high degree of preparedness.

10 Sodium Valproate: Inquiry

It was noted that the Department of Health had issued a press release announcing the Minister for Health is committed to holding an inquiry into the historical licensing and use of the anti-epileptic drug sodium valproate in Ireland. This followed a meeting with representatives from Epilepsy Ireland and the Organisation for Anti-Convulsant Syndrome (OACS) Ireland.

While the structure and format is not yet confirmed, the HPRA is fully committed to co-operating with the inquiry.

11 HPM Update: Covid and Safety Monitoring

A presentation was given by the Director of Human Products Monitoring (HPM), which set out key considerations for the HPM department in light of Covid-19 activities. Specific items included: the role of HPM over the regulatory lifecycle of Covid-19 vaccines; special considerations for pandemic vaccine monitoring; preparedness planning; key readiness activities; and risk mitigations.

The Chairperson and Authority commended the Director of HPM for the level of preparedness of the department.

12 Irish Blood Transfusion Service (IBTS) Annual Report

The 23rd annual report to the Minister for Health by the HPRA in relation to the IBTS was noted.

The Chief Executive provided an overview of the future arrangements between the IBTS and the HPRA. A meeting to formalise the arrangements between the two agencies on haemovigilance took place in December 2020, with a further meeting planned in January 2021.

The Authority approved the annual report.

13 Authority Matters

Conflict of Interest Policy

The document was noted by the Authority, with no amendments recommended. It was suggested that training on this item should be scheduled for 2021 to ensure all Authority members are familiar with the policy. The Secretary will undertake these arrangements.

Authority Calendar 2020

The Authority agreed that all the Authority Calendar 2020 items were completed.

14 2021 Budget for Approval

The Deputy Chief Executive presented the 2021 budget, which was recommended to the Authority by the Audit and Risk Committee.

The 2021 budget, with revised deficit figure, was approved by the Authority.

15 Reflection

On their final Authority meeting, the Chairperson, Prof O'Driscoll and Prof Kerins gave reflections on their time on the Authority and respective Committees.

They noted how the organisation has progressed and the crucial role of the Authority in overseeing development of the HPRA profile both nationally and internationally.

The significant contributions, professionalism and dedication of the outgoing Chairperson and Authority members were acknowledged by the Chief Executive and the Management Committee.

16 Committees

ITEM	Statutory Committee	Last Meeting Date	Updates
16.1	Audit and Risk Committee (ARC)	01/12/2020	<p>Key issues outlined included:</p> <ul style="list-style-type: none"> • Mortgage repayment: The ARC recommended to the Authority an accelerated mortgage repayment schedule. The Authority discussed the proposal which was agreed and approved. • Internal audit reports on Payroll, Travel and Subsistence, and Human Resources were outlined. • A brief update on the current internal audit plan was provided. • A review of impact of COVID-19 on HPRA Control Environment had been conducted, based on guidance issued by the Office of the Comptroller and Auditor General. Many of the controls already in place pre-COVID continue to apply in the current environment. Both internal and external audit reviews had taken place remotely, and no weaknesses were identified. • It was noted that the 1 December meeting was Prof O'Driscoll's final ARC meeting.
16.2	Advisory Committee for Veterinary Medicines (ACVM)	16/09/2020	No updates to report.
16.3	Advisory Committee for Medical Devices (ACMD)	23/11/2020	The Chair provided a verbal update on the recent meeting, and the Chair's report was noted by the Authority. The Authority Chairperson thanked Prof Reilly for his work with the Committee.
16.4	Advisory Committee for Human Medicines (ACHM)	03/12/2020	The Chair provided a verbal update on the recent meeting. The Authority Chairperson thanked Prof Kerins for his time as both Chair and also member of the ACHM.

17 Finance

The Authority noted the Management Accounts for September and October 2020.

18 Licensing Activities

The Authority noted the tables of licenses approved by the Management Committee during the period 30/10/2020 to 27/11/2020.