

Wednesday, 24 May 2023, 2.00 pm (hybrid meeting)

Report of the Authority

Chair	Mr M. Donnelly
Present	Dr P. Kilbane, Prof S. O’Kane**, Dr J. Collins* **, Dr D. Quinlan**, Dr F. Kiernan, Mr B. Jones*, Prof R. Reilly
In attendance	Dr L. Nolan, Chief Executive; Ms. R. Purcell**, Deputy Chief Executive; Board Excellence * **, Dr F. Lonsdale*, Director of HPAR; ENSUS project manager*
Apologies	Mr D. Holohan
Minutes	Ms K. Murphy, Secretary to the Committees

*attended for part of meeting

**attended the meeting remotely

1 Welcome and Introductions

The Chair welcomed the members to the Authority meeting.

The Chair also welcomed the representative from Board Excellence to the meeting and informed Authority members that the representative would be attending the meeting in an observational capacity.

2 Declarations of interest/Conflicts of Interest

Prof S. O’Kane and Dr P. Kilbane noted their conflicts as per the annual declarations received.

3 Financial Statements for the year ended 31 December 2022

The Authority was reminded of its responsibilities for the financial statements and the statement of governance and internal control. It was noted that the recent C&AG audit had been successfully completed and the C&AG was satisfied with the financial statements. Key items in the financial statements were outlined to the Authority by the Deputy Chief Executive. It was noted that the ARC had reviewed the financial statements in detail and recommended them to the Authority. The Authority adopted the:

- 2022 Statement of Governance and Internal Control Statements
- 2022 Financial Statements
- The reconciliation between the Financial Statements and the December Management Accounts

The Chairperson’s Report 2022 was taken as read.

*Board Excellence representative left the meeting

4 Sodium Valproate

Possible next steps regarding the Sodium Valproate review were discussed. It was noted that the terms of reference (ToR) have not yet been published. Once received, the ToRs will be circulated to the Authority.

*Ms R. Purcell left the meeting.

5 Report of the meeting April 2023

* Board Excellence representative joined the meeting.

The report of the meeting of 05 April was approved.

6 Health and Safety Update

There was nothing to report.

7 Chief Executive's update

Specific points discussed included:

Medicines Availability

As part of ongoing national collaboration efforts to address medicines availability in Ireland, the HPRA shortages lead attended an Irish College of General Practitioners (ICGP) meeting as well as a meeting of the Irish Medication Safety Network to discuss shortages. The HPRA also presented at a meeting of the Irish Institute of Pharmacy on shortages.

The Chief Executive outlined on-going work with the Department of Health and the HSE on joint communications in the area of shortages. Planned activities include a technical briefing to be given to health journalists and correspondents. A briefing for journalists is scheduled for June 12.

Revision of the Pharmaceutical Legislation

The Authority was informed that it has been 22 years since the current pharmaceutical Directive was amended. Following the development of a pharmaceutical strategy for Europe, the Commission has published a draft Regulation and Directive with substantive proposed updates to the legislation. Among the proposed aspects of the updated legislation outlined to the Authority, was the modulated periods of data protection and market exclusivity, provisions to support innovation, simplified regulatory processes. It was also noted that there was a focus on shortages, accessibility to medicines, AMR and the environment. The next step is that the draft legislation will be negotiated at the council working parties under the Presidency.

The draft legislation is broadly welcomed by the HPRA and work on a national response, remains ongoing with the Department.

Patient Forum

The Authority was informed of the launch of the HPRA's Patient Focused Approach module which is a new training module for all colleagues. The Authority was also informed of the upcoming launch of the HPRA patient speaker programme on the 1 June 2023. The programme panel will comprise of Dr E. Dorris, Ms J. Browne, and Ms M. Daly who will discuss the importance of Patient Public Involvement (PPI) as well as their own experiences. The event will be held in the HPRA offices with all HPRA colleagues invited. Invitations were also extended to the Authority members. The efforts of all those involved in organising the event were commended, particularly Dr Kilbane as Chair of the Patient Forum.

*Dr J. Collins and Mr B. Jones left the meeting

8 Midterm Review of the Strategic Plan

Oral update on next steps

Thanks were extended to Dr Kiernan, Professor O’Kane, and Mr Jones for agreeing to be involved in the midterm review of the current HPRA Strategic Plan. As part of the review, three workshops will be established which will review the five strategic goals identified and outlined in the plan. The review will consider if the objectives and key deliverables of the goals remain relevant and will recommend changes where necessary. Members of the HPRA leadership team as well as senior managers will also be involved. The initial outcomes of the workshops will be discussed at the next Authority meeting in September.

9 Human Products Authorisation Registration Overview

*Dr F. Lonsdale and Mr B. Jones joined the meeting

An overview was given of the Human Products Authorisation and Registration (HPAR) department by the HPAR Director. HPAR is the largest department in the organisation accounting for approximately one third of all staff members. The overview outlined the work undertaken by HPAR at both national and EU level, including current priorities and developments.

The allocation of work and the centralised EMA ranking of the organisation were discussed. The challenges and opportunities facing the department were outlined. These included rolling reviews, which require tight turnaround times, and the introduction of the Clinical Trials Regulation which will require increased resources. Other potential challenges and opportunities include the revision of the pharmaceutical legislation, which, although not yet finalised, will reconsider committee structures and timelines, as well as a sustainable operating model and capacity levels.

In light of the number of developments at hand, it was agreed that a further update would be provided at an Authority meeting in the near future.

*Dr F. Lonsdale and Mr B. Jones left the meeting

10 September Strategic Discussion

Oral update on next steps

A roadmap following on from the last strategic discussion will be circulated to members four weeks ahead of the next discussion planned for September.

11 Energy and Sustainability Project Update

*ENSUS project manager joined the meeting

The Authority was briefed on the ENSUS project, and the HPRA’s progress in reaching its targets under the Government’s Climate Action Plan which is to reduce energy use by 50% and greenhouse gas (GHG) emissions by 51% by 2030. As required by the Climate Action Plan, the HPRA has established a Climate Action Roadmap which includes information on engaging and training staff, greening procurement, baselining and reducing resource use, and improving buildings. Specific activities by the ENSUS team in 2022/2023 were also outlined. The Authority commended the good work being undertaken by the ENSUS team, membership of which is voluntary.

Climate Action Roadmap

The HPRA's Climate Action Roadmap, which was provided to members in advance of the meeting, was noted.

* ENSUS project manager left the meeting

12 Committee updates

Statutory Committee	Last Meeting Date	Updates
Audit and Risk Committee (ARC)	17 May 2023	The ARC recommended the financial statements to the Authority.
Advisory Committee Veterinary Medicines (ACVM)	None since last meeting	N/A
Advisory Committee Medical Devices (ACMD)	None since last meeting	N/A
Advisory Committee Human Medicines (ACHM)	None since last meeting	N/A

13 AOB

Succession planning

Work on succession planning is ongoing both in relation to the senior leadership team as well as the Authority. To support the considerations of the Authority in relation to succession planning, a skills and competence questionnaire will be circulated to the members following the meeting.

The matter will be tabled again at the Authority meeting in September.

14 2023 Authority Calendar

The Authority calendar for the upcoming year was noted and the Authority was reminded that it is a living document subject to change.

15 HPRA updates (Changes to legislation, Competencies, Code of Conduct etc.)

- Misuse of Drugs (Amendment) Regulations 2023 (SI 150/2023)
- Misuse of Drugs (Amendment) (No.2) Regulations 2023 (SI 156/2023)
- Misuse of Drugs (Prescription and Control of Supply of Cannabis for Medical Use) (Amendment) (No. 2) Regulations 2023 (SI 200/2023)

16 Finance Accounts – February and March 2023

The Authority noted the management accounts for February and March 2023.

17 Licensing Activities – Tables of Licences Approved

The Authority noted the availability of the tables specifying the authorisations approved by the HPRA Leadership Team during the period 31/03/2023 to 12/05/2023.