

Report of the Authority

- 26 November 2025 at 14.00

Chair	Mr Michael Donnelly;
Present	Mr D. Holohan; Mr B. Jones*; Dr J. Collins; Dr F. Kiernan; Prof R. Reilly; Dr P. Kilbane; Prof S. O’Kane;
In attendance	Dr L. Nolan, Chief Executive; Ms Grainne Power, Director of Compliance; Ms R. Purcell, Deputy CEO*; Mr Laurence O’Dwyer, Scientific Affairs Manager*; Mr Sean d’Art, Director of ICT and Business Services*; Ms Aisling Holly, Corporate Affairs Manager
Apologies	-

- Minutes taken by Ms K. Murphy, Secretary to the Committees and Administrative Coordinator Finance, Corporate & International
- * Attended for part of the meeting
- ** Attended the meeting remotely

1 WELCOME AND INTRODUCTIONS

This was the last meeting for the Chair as well as Prof S O’Kane whose terms will conclude at the end of the year. The Chair welcomed the incoming Chief Executive, Ms Grainne Power to the meeting and acknowledged that it was also the last meeting for Dr Nolan whose 10-year tenure will conclude in January 2026.

2 DECLARATIONS OF INTEREST/CONFLICTS OF INTREST

Prof S. O’Kane, Dr P. Kilbane, Dr J. Collins, and Dr F. Kiernan noted their respective declared interests as per their annual declarations.

3 REPORT OF THE MEETING OF 10 SEPTEMBER 2025

The report of the meeting of 10 September 2025 was approved.

4 HEALTH AND SAFETY

4.1 Safety statement

The amended safety statement was approved following agreement to include reference to the Authority.

5 CHIEF EXECUTIVE’S UPDATE

5.1 Strategic development of medicines availability management

A meeting is planned with the Department of Health to discuss the proposed medicines availability management group. This will consider availability at wholesale level, a revised governance structure and establishing a cohesive national approach. The HPRA has also established its own Medicines Availability Group to consider digital infrastructures both internally and how they interface with other relevant EU systems which will be a key focus during 2026. The Authority recognised the potential impact on the public of medicines shortages.

5.2 NSAI

An update was provided on NSAI following the suspension of its MDR designation earlier in the year. Discussions between the HPRA and NSAI are ongoing and next steps were considered. A further update will be provided to the Authority in January.

5.3 Changes in leadership

The recent appointment of Ms Nicola Riggs as the Director of Human Resources and Development as well as the appointment of the incoming Finance, Corporate and Legal Director were noted. Thanks were extended to the Authority members who were involved in the recruitment processes for both roles. The Authority welcomed the appointments and noted the planned finish date for Ms Purcell in January 2026 and the planned renaming of the Finance, Corporate and International Department to the Finance, Corporate and Legal Department following internal restructuring. Following the appointment of Ms Grainne Power to the role of Chief Executive, work is underway in relation to filling her outgoing role as Director of Compliance.

5.4 Employee experience survey 2025

The employee experience survey was conducted in September 2025 with an overall engagement rate of 72% which was an increase of 7% on the previous year. Career development needs will remain a focus of 2026 and a career capability framework was launched earlier in the week to support this. Leadership and communication will also remain as a key focus. Department action plans will target department specific issues and areas of improvement. The planned changes to the PDP programme in 2026 were also highlighted.

5.5 Irish Presidency of the Council of the European Union 2026

An update was provided on the Irish Presidency of the Council of the European Union which is planned to commence in June 2026. Discussions relating to the final meeting schedule and funding remain ongoing with the Department of Health. The Authority role in the Presidency, if any, is still under consideration.

5.6 NIS2 and the EU AI Act

*Prof R. Reilly joined the meeting

An update was provided on engagement with the Department of Health regarding the possible appointment of the HPRA as the Competent Authority for NIS2. The external review of the potential HPRA's designation under NIS2 was discussed.

Under the AI Act, the HPRA has been named as a Market Surveillance Authority and Notifying Authority for medical devices. The potential impact of the Act in terms of obligations, data protection and resourcing as well as the overlap with the IVDR remains unclear. The planned European Commission Digital Omnibus is anticipated to address some of these uncertainties and overlaps.

An ongoing digital health project being undertaken by medical device colleagues is planned to be presented to the Authority in 2026 and digital health in general remains under consideration internally. This topic will be returned to the Authority for further consideration in 2026.

6 DEPUTY CEO UPDATE

*Ms R. Purcell joined the meeting

6.1 Budget 2026

The Deputy Chief Executive presented the budgets for 2026, which were recommended to the Authority by the Audit and Risk Committee (ARC). The detailed budgets of the HPRA were reviewed and, following a discussion, were approved by the Authority.

6.2 Sodium Valproate

The HPRA's recent submission to the Chair of the Sodium Valproate non-statutory inquiry was noted. Authority members acknowledged both the comprehensive nature of the detailed submission and the contribution of the HPRA team involved in its development. The HPRA remains available to the inquiry to address any follow-up questions that may arise and will keep the Authority informed.

6.3 Pensions

It was noted that the position in relation to pensions was unchanged from the previous Authority update. The Department of Public Expenditure has established a committee to review agencies under the aegis of the Department of Health which are not fully funded by the exchequer with a view to considering the issue of unfunded pension liabilities related to the LGSS scheme, but those discussion are ongoing.

Post meeting note: As part of the ongoing engagement with the Department of Health, an email received noted that the issue of pensions can be considered further as part of the annual subvention.

*Ms R. Purcell and Mr B. Jones left the meeting

7 HPRAs UPDATES (CHANGES TO LEGISLATION, COMPETENCIES, TOR, CODE OF CONDUCT ETC.)

7.1 Conflicts of Interest Policy

*Mr L. O'Dwyer joined the meeting

The proposed changes to the HPRAs Conflicts of Interest Policy were discussed. The changes are aimed at further aligning the HPRAs policy with the EMAs. The Authority approved the proposed Conflicts of Interest Policy changes for staff but requested that a separate policy be created for Authority and Committee members as well as external experts to avoid confusion. It was agreed that, going forward, an annual review of the Conflicts of Interest will be undertaken by the ARC.

*Mr L. O'Dwyer left the meeting

7.2 Changes to legislation

- Medicinal Products (Prescription and Control of Supply) (Amendment) (No. 2) Regulations 2025 (SI 418/2025)
- Medicinal Products (Prescription and Control of Supply) (Amendment) (No. 3) Regulations 2025 (SI 502/2025)
- Medicinal Products (Control of Placing on the Market) (Amendment) Regulations 2025 (SI 504/2025)

8 STRATEGIC PLAN 2026-2028

An update was provided on the draft HPRAs Strategic Plan 2026-2028. As part of next steps, a number of Authority members will work closely with the incoming Chief Executive to further review the four proposed pillars and the outcomes expected under each. The draft plan is expected to be returned to the Authority meeting in January 2026 for final approval.

9 IT DIRECTOR-CYBER SECURITY

*Mr S. d'Art joined the meeting

An update was provided on cyber-security measures within the organisation. Emphasis was placed on proactiveness and business continuity with security awareness training being rolled out to all staff earlier in the year. Older systems are also being decommissioned. The budgetary requirements for cyber security may need to be reviewed in 2027. A further update was also provided on NIS2 and the potential regulatory obligations for the HPRAs in complying with the Directive.

*Mr S. d'Art left the meeting

10 2026 SERVICE PLAN

The 2026 Service plan was taken as read and adopted by the Authority.

11 COMMITTEE UPDATES

Statutory Committee	Last meeting date	Updates
Audit and Risk Committee (ARC)	26 November 2025	<p>An update was provided by the ARC Chair, Mr D. Holohan, following the meeting on 26 November. This was the last ARC meeting for Prof S. O’Kane, Mr B. Jones and also the ARC Chair who extended his thanks to the outgoing members for all their expertise and dedication throughout the years as well as the ARC secretary for their support. The ARC requested that training courses, in particular financial training, be considered for all members of the Authority. The Authority Chair extended his sincere thanks to the ARC Chair for his exemplary Chairmanship. The 2025 ARC internal review was provided to members.</p> <p>The signed minutes from the 28 May 2025 ARC meeting were provided to the Authority.</p>
Advisory Committee Veterinary Medicine (ACVM)	29 October 2025	The ACVM Chair report on the recent meeting of the ACVM was noted.
Advisory Committee Medical Devices (ACMD)	N/A	N/A
Advisory Committee Human Medicines (ACHM)	N/A	N/A

12 AOB

The Authority Chair extended his sincere thanks and appreciation to all outgoing members as well as the Chief Executive.

12.1 Authority self-evaluation 2025

The results of the Authority self-evaluation were provided for information.

13 FINANCE ACCOUNTS

The Authority noted the management accounts for August to September 2025.

14 LICENSING ACTIVITIES

The Authority noted the tables provided specifying the authorisations approved by the HPRA Leadership Team during the period 29/08/2025 to 07/11/2025.