

## Report of the Authority

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- 10 September 2025 at 13.00 (hybrid meeting)

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<b>Chair</b>	Mr Michael Donnelly;
<b>Present</b>	Mr D. Holohan; Mr B. Jones; Dr J. Collins; Dr F. Kiernan; Prof R. Reilly; Dr P. Kilbane; Prof S. O’Kane; Dr S. Kelly**;
<b>In attendance</b>	Dr L. Nolan, Chief Executive; Ms R. Purcell, Deputy CEO; Ms E. Hynes, Operational Excellence Manager*;
<b>Apologies</b>	

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- Minutes taken by A. Holly, Corporate Affairs Manager
- \* Attended for part of the meeting
- \*\* Attended the meeting remotely

### 1 WELCOME AND INTRODUCTIONS

The Chair welcomed the members to the Authority meeting.

### 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 28 MAY 2025

The report of the meeting of 28 May 2025 was approved.

### 4 HEALTH AND SAFETY

There was nothing to report.

### 5 CHIEF EXECUTIVE’S UPDATE

At the outset of the meeting, the Authority paid tribute to the late Prof. Pat O’Mahony, former Chief Executive of the HPRA. Members acknowledged his significant contribution to the organisation and to healthcare regulation in Ireland. During his tenure, he oversaw the 2014 rebranding of the Irish Medicines Board (IMB) to HPRA and was instrumental in the development of many key initiatives. He also served as Chair of the national expert taskforce on the expansion of the role of pharmacists in Ireland, and as Chair of HIQA. The Authority expressed its deep appreciation of his service and extended condolences to his family.

### **5.1 Sodium Valproate**

The Authority received an update on the HPRA preparation for the non-statutory inquiry into the licensing and use of sodium valproate in women of child-bearing potential.

### **5.2 Codeine Classification Review**

The Authority received an update on the ongoing review of the classification of low-dose codeine medicines. It is anticipated that the initial assessment stage will be concluded during the first quarter of 2026. The Authority acknowledged the importance of following a fair and consistent process.

### **5.3 The National Standards Authority of Ireland (NSAI)**

The recent joint reassessment of the National Standards Authority of Ireland (NSAI) as a notified body under the EU Medical Devices Regulation was discussed. This reassessment forms part of the mandatory process whereby notified bodies are reviewed five years after their initial designation, to confirm continued compliance with the regulatory requirements.

### **5.4 The Presidency 2026**

The Authority considered progress in preparations for Ireland's Presidency of the Council of the European Union in the second half of 2026. The HPRA will host a series of expert meetings on behalf of the European medicines regulatory network. Venue and logistical planning for the meetings has commenced. The HPRA continues to engage closely with the Department of Health and the Department of Foreign Affairs.

### **5.5 HPRA Business**

The Authority welcomed the appointment of Dr David Murphy as Director of Veterinary Sciences following the retirement of Dr Gabriel Beechinor. Recruitment processes for the Director of Finance, Legal and Corporate Affairs, and for the Director of Human Resources and Development are well advanced, with interviews scheduled in September and October. Interim arrangements will be in place from the end of September pending a permanent HRD appointment.

The Authority also received an update on the HPRA's prospective responsibilities under the EU Network and Information Security Directive (NIS2) and the Artificial Intelligence Act. An external assessment has provided recommendations on governance and capability development, and discussions with government partners continue the scope of HPRA's role.

## **6 SERVICE PLANNING-2025 HALF YEAR REPORT**

\*Ms E. Hynes joined the meeting

## **6.1 Half year progress report 2025**

The progress to date of the 2025 Service Plan was reviewed, with the status under each of the five strategic goals outlined and discussed. As of June, 15% of activities had been completed, 67% remained on target, 9% were experiencing minor delays, and 9% had yet to commence. It was agreed that future reporting will be streamlined to focus on the impact being delivered rather than on activity counts. A one-page dashboard will be developed to provide a high-level overview of key activities and deliverables, with operational excellence highlighted as a core dimension. Work is continuing to refine timelines and to sequence activities effectively across all four quarters. The Service Plan and dashboard will provide an integrated, cross-organisational perspective, demonstrating both requirements and collective organisational output.

## **6.2 2025 high level business planning**

The key priorities for the strategic goals under the 2025 Service Plan were outlined. Members agreed that the forthcoming pharmaceutical legislation represents a significant priority for 2026, given its potential impact on regulatory requirements, compliance frameworks, service delivery models, and stakeholder engagement. The organisation will need to prepare for the introduction of the new legislation and its impact on the operation of the HPRA. To support this work, preparatory analysis and scoping will take place once the legislation is finalised. A dedicated project team will be established in 2026 to commence the process of the implementation both from the development of secondary legislation and operational impacts. The timelines will depend on the date of publication of the legislation and the transition period laid down in the Directive.

\*Ms E. Hynes left the meeting

## **7 UPDATE ON SUCCESSION WITHIN THE HPRA LEADERSHIP TEAM-PROGRESS OVER 2025**

\*Ms R. Purcell joined the meeting

A further update was provided in relation to succession planning for the HPRA executive following a previous update which was provided at the Authority meeting on the 27 November 2024.

## **8 IBTS 28<sup>TH</sup> ANNUAL REPORT**

The HPRA's 28th annual report to the Minister for Health on the Irish Blood Transfusion Service, for the year 2024, was provided to the Authority for approval.

## **9 HPRA STRATEGY 2026-2029**

The Authority noted that the current strategy expires at the end of 2025 and considered the draft HPRA Strategy, which is designed to set a clear course for future regulatory challenges. The draft has been informed by extensive engagement with national stakeholders and European partners, and reflects priority themes including digital transformation, the application of artificial intelligence, and evolving health policy.

Members emphasised the need for a strategy that is both ambitious and adaptable, with structured review points ensuring the organisation can respond swiftly to a dynamic external environment. It was noted that 2026, which marks the 30th anniversary of the HPRA, will provide an appropriate context in which to launch the new strategy and highlight the Authority’s long-standing contribution to public health. Finalisation will take place following the appointment of a new Chief Executive, who will have the opportunity to shape the document prior to submission to the Department of Health.

\*Ms R. Purcell left the meeting

## 10 COMMITTEE UPDATES

Statutory Committee	Last meeting date	Updates
Audit and Risk Committee (ARC)	10 September 2025	<p>A summary paper of the ARC 10 September meeting was provided to members in advance of the Authority meeting. The update included</p> <ul style="list-style-type: none"> <li>- Risk Register</li> </ul> <p>The risk register was reviewed, three new risks were noted. Current risks are classified across high, medium, and low categories.</p> <p>The signed minutes from the 28 May 2025 ARC meeting were provided to members.</p>
Advisory Committee Medical Devices (ACMD)	26 May 2025	The ACMD Chair report on the recent meeting of the ACMD was noted.
Advisory Committee Human Medicines (ACHM)	09 April 2025	The ACHM Chair report on the recent meeting of the ACHM was noted.
Advisory Committee Veterinary Medicine (ACVM)	N/A	N/A

## 11 AOB

### 11.1 HPRA Annual Report 2024

The 2024 HPRA Annual Report was provided for information and was taken as read.

### 11.2 Patient Forum Annual Report 2024

The 2024 Patient Forum Annual Report was adopted.

### 11.3 HPRA Website project-technical, financial and project governance overview

The website project-technical, financial and project governance overview was provided for information and was taken as read.

## **12 HPRa UPDATES – CHANGES TO LEGISLATION COMPETENCIES, CODE OF CONDUCT ETC.**

### **12.1 Terms of Reference**

- Authority

The proposed updates to MGT-P0007 Terms of reference and rules of procedure of the HPRa v20d1 were reviewed and adopted.

- HPRa Leadership Team

The proposed updates to MGT-P0008 Terms of reference and rules of procedure of the HPRa Leadership Team v8 were reviewed and adopted.

- Audit and Risk Committee

The proposed updates to MGT-P0013 Terms of reference and rules of procedure of the Audit and Risk Committee v7 were reviewed and adopted.

### **12.2 Changes to legislation**

- European Union (Artificial Intelligence) (Designation) Regulations 2025 (SI 366/2025)
- Data Protection Act 2018 (Section 38(4)(B)) (Inquiry into the Licensing and Use of Sodium Valproate in Women of Child-Bearing Potential in the State) Regulations 2025 (SI 350/2025)
- Data Protection Act 2018 (Section 51(3)) (Inquiry into the Licensing and Use of Sodium Valproate in Women of Child-Bearing Potential in the State) Regulations (SI 351/2025)
- Data Protection Act 2018 (Section 60(6)) (Inquiry into the Licensing and Use of Sodium Valproate in Women of Child-Bearing Potential in the State) Regulations 2025 (SI 352/2025)
- Misuse of Drugs (Prescription and Control of Supply of Cannabis for Medical Use) (Amendment) Regulations 2025 (SI 229/2025)
- Medicinal Products (Prescription and Control of Supply) (Amendment) Regulations 2025 (SI 353/2025)
- Misuse of Drugs Act 1977 (Controlled Drugs) (Declaration) Order 2025 (SI 404/2025)
- Misuse of Drugs (Amendment) Regulations 2025 (SI 405/2025)
- Misuse of Drugs Act 1977 (Controlled Drugs) (Designation) (Amendment) Order 2025 (SI 406/2025)

## **13 FINANCE ACCOUNTS**

The Authority noted the management accounts for April to July 2025.

## **14 LICENSING ACTIVITIES**

The Authority noted the tables provided specifying the authorisations approved by the HPRA Leadership Team during the period 16/05/2025 to 10/09/2025.