HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

Report of the Authority

- Wednesday 29 January 2025 at 15.00 (hybrid meeting)

Chair	Present	In attendance	Apologies
Mr M. Donnelly	Prof S. O'Kane	Dr L. Nolan, Chief Executive*	
	Dr J. Collins	Corporate Affairs Manager	
	Dr F. Kiernan	Mr S. d'Art, Director of ICT and Business Services*	
	Prof R. Reilly	EY Partner, Health Sector Leader*	
	Mr D. Holohan	EY Manager, Business Consulting*	
	Dr P. Kilbane	EY Senior, EYP-Strategy*	
	Dr S. Kelly		
	Mr B. Jones*		

- Minutes taken by Ms K. Murphy, Secretary to the Committee
- * 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 INTEREST

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

3 EY STRATEGIC OVERVIEW

*EY attendees joined the meeting

An update was provided on the review by EY in relation to the HPRA strategic plan 2026-2028. Preliminary results from the data gathering, undertaken using a variety of methods such as internal and external quantitative and qualitative analysis, were shared with the Authority. Areas of key consideration for the organisation over the lifespan of the strategy were highlighted such as the 2026 Irish presidency of the EU council, new EU legislation, the regulatory environment and the impact of AI on areas HPRA regulate and for the HPRA operational environment. Members also reflected on the role of the HPRA in both the national and European regulatory landscape. The primary strategic themes will be further reviewed by the Authority.

*EY attendees left the meeting

4 REPORT OF THE MEETING 27 NOVEMBER 2024

The report of the meeting of 27 November will be circulated to members after the meeting for approval.

5 HEALTH AND SAFETY

There was nothing to report.

6 CHIEF EXECUTIVE'S UPDATE

Specific points discussed included:

6.1 Classification review of low-dose codeine medicines

An update was provided in relation to the HPRA's ongoing classification review of low-dose codeine medicines. It was noted that if the outcome of the review resulted in a recommendation to up classify low dose codeine products there will also be implications for the wider delivery of health services under the remit of the Department of Health.

6.2 Working arrangement with the IBTS

A trilateral meeting was held between the HPRA, the Department of Health and the Irish Blood Transfusion Service's (IBTS) National Haemovigilance Office to outline the next steps in streamlining hemovigilance reporting.

6.3 Veterinary medicines national forum

The veterinary medicines national forum "kick-off" meeting took place on 6 January with the next meeting planned for March.

6.4 Proposed designation of HPRA as CA under NIS2

Discussions regarding the proposed designation of the HPRA, and its suitability as a competent authority under NIS2 remain ongoing with the Department of Health.

6.5 EU AI Act

Discussions continue with the Department of Health and the Department of Enterprise Trade and Employment regarding the proposed appointment of the HPRA as a market surveillance authority for medical devices under the EU AI Act.

6.6 IBEC KeepWell Mark reaccreditation

The Authority extended its congratulations to the HPRA for the reaccreditation of its Keepwell mark which recognises continuous commitment to improving employees' health and wellbeing.

6.7 National Diversity and Inclusion Awards 2025

The HPRA has been shortlisted for the public sector organisation of the year.

6.8 Strengthening medicines regulation in Sub-Saharan Africa

The HPRA was successfully awarded an EMA grant to help strengthen medicine regulatory systems in Sub-Sahara Africa. As a result, the HPRA will deliver two five-day GMP new inspector training courses in March to inspectors from the African Medicines Agency.

7 WEBSITE UPDATE

*Mr S. d'Art joined the meeting

The new HPRA website, which went live on the 28 January, was highlighted to members. The enhanced accessibility of the site will remain a key focus while work remains ongoing on the decommissioning of the legacy website. Regular reminders are being issued to encourage stakeholders to subscribe to the email alerting service available on the new website. A new governance policy is in place to ensure the integrity of the site, and there will be periodic reviews of the content quality and accessibility. Any new colleagues provided with access to the website will be required to complete CMS and writing for the web training.

*Mr S. d'Art and Mr B. Jones left the meeting

8 COMMITTEE UPDATES

Statutory Committee	Last meeting date	Updates
Audit and Risk Committee (ARC)	26 November 2024	The 2024 ARC annual report was provided to members in addition to the signed minutes from the 25 September 2024 ARC meeting.
Advisory Committee Veterinary Medicines (ACVM)	N/A	N/A
Advisory Committee Medical Devices (ACMD)	N/A	N/A
Advisory Committee Human Medicines (ACHM)	11 and 18 December 2024	An update on the recent meeting of ACHM was provided.

9 AOB

There was nothing to report.

10 HPRA UPDATES – CHANGES TO LEGISLATION COMPETENCIES, CODE OF CONDUCT ETC.

- European Union (Cosmetic Products) (Amendment) Regulations 2024 (SI 637 /2024)
- European Union (General Product Safety) Regulations 2024 (SI 726/2024)
- Health Products Regulatory Authority (Fees) Regulations 2024 (SI 751/2024)
- Health (Miscellaneous Provisions) Act 2024 (Commencement) (No. 2) Order 2024 (SI 753/2024)

10.1 Finance accounts- October 2024 and November 2024

The Authority noted the management accounts for October and November 2024.

11 LICENSING ACTIVITIES - TABLES OF LICENCES APPROVED

The Authority noted the tables provided specifying the authorisations approved by the HPRA Leadership Team during the period 15/11/ 2024 to 10/01/2025.