HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

Report of the Authority

- Wednesday 25 September 2024 at 2pm (hybrid meeting)

Chair	Present	In attendance	Apologies
Mr M. Donnelly	Prof S. O'Kane	Dr L. Nolan, Chief Executive	Dr D. Quinlan
	Dr J. Collins	Ms R. Purcell, Deputy Chief Executive*	
	Dr F. Kiernan**	Corporate Affairs Manager	
	Mr B. Jones		
	Prof. R. Reilly		
	Mr D. Holohan		
	Dr P. Kilbane		

- Minutes taken by Ms K. Murphy, Secretary to the Committee
- * Attended for part of the meeting
- ** Attended the meeting remotely

1 CLOSED SESSION OF THE AUTHORITY

A closed session of the Authority was held before the Authority meeting. The closed session was attended by members of the Authority and Mr John Kennedy, senior counsel.

2 WELCOME AND INTRODUCTIONS

The Chair welcomed the members to the Authority meeting.

3 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.

4 REPORT OF THE MEETING OF 8 MAY 2024

The report of the meeting of 8 May 2024 was approved.

5 HEALTH AND SAFETY

5.1 HPRA Safety Statement

The updated HPRA Safety Statement was adopted by the Authority. Changes include recommendations from IBEC relating to the removal of references to Covid-19.

6 CHIEF EXECUTIVE'S UPDATE

Specific points discussed included:

6.1 Supply of compounded medicines

An update was provided regarding the voluntary, temporary suspension of the manufacturing of compounded medicines at a manufacturing site. Mitigation steps undertaken to ensure the continuity of supply included the importation of product from the UK and the increase of on-site compounding by hospitals nationally. While some interruption to patient treatments occurred, supply levels are expected to stabilise.

6.2 Reinitiation of the sodium valproate stakeholder group

The Authority was informed that the group had reconvened on 16 July with the next meeting due to be held in September. Commitment has been received from the HSE to increase reports of usage in pregnancy in relation to sodium Valproate. The HPRA provides information to the group on the current risk minimisation requirements in relation to the prescribing of sodium valproate.

6.3 HPRA website redevelopment project

Work remains ongoing on the redevelopment of the website. Content migration is projected to be completed by the end of October. Of the four planned deliveries, three have been released and are undergoing testing. Planning for transition and communications to stakeholders are ongoing.

6.4 Brexit and Windsor Framework – Human medicines

Under the Windsor Framework, set to come into effect January 2025, joint labelling on medicine packs between the UK and Ireland will no longer be possible. The HPRA continues to work with companies to minimise the impact of the Windsor Framework on the supply of medicines to the Irish market. The HPRA is also closely engaging with the Department of Health and the MHRA in the UK.

6.5 Brexit and Windsor Framework – Veterinary medicines

Exemptions under the NI Protocol for veterinary medicinal products will expire at the end of December 2025. The HPRA does not expect any impact on supply to the Irish (IE) market. The situation in Northern Ireland (NI) is very different with up to 70% of medicines relying on the Brexit exemptions. It is not known whether a solution will be negotiated but given the significant use of joint labels between UK and Ireland, it is hoped that any solution will not impact supply to IE while protecting supply to NI.

6.6 Medicines regulatory systems strengthening in Sub-Saharan Africa

The Authority supported the HPRA's submission of a proposal for an EMA grant for initiatives to support strengthening of regulatory systems in Sub-Sharan Africa. As the HPRA has a long history of training inspectors, having run its week-long good manufacturing practice (GMP) New Inspector Training Programme since 2011, the proposal relates to the training of 10 inspectors from the African Medicines Agency. The training will be offered in conjunction with NIBRT in March 2025 and aims to benefit the global regulatory network by strengthening inspectorates and ensuring a more harmonised approach.

6.7 Critical Entities Resilience Directive (CERD)

The application of the CERD to the HPRA was confirmed by the Department of Health in June. Under the CERD, the HPRA will be responsible for ensuring that essential entities have sufficient resilience in place to ensure continuity of supply. Under the scope of the CERD, critical manufacturers of medicines, wholesalers and research organisations will fall under the remit of the HPRA. The alignment between the new requirements and the inspection activities currently undertaken by the HPRA was highlighted. Preparation activities will be undertaken throughout 2025 and 2026 with inspections commencing in 2027. Next steps include the consideration of resourcing to support the implementation of CERD.

6.8 Expanded Network and Information Security Directive

At the end of November 2023, the Department of Health adopted a sectoral based approach to the implementation of NIS2. In June, the HPRA was informed that under NIS2 it will be responsible for the governance and oversight of the risk mitigation and risk assessment measures of organisations within its scope. Concerns were raised regarding the specialist technical skills and resourcing requirements, as well as the organisations under the scope of the Directive and engagement continues with the Department on these matters. To assist the organisation to adequately prepare for and support the NIS2, an external scoping exercise will be undertaken.

7 SERVICE PLANNING

*The Operational Excellence manager joined the meeting

7.1 Half year progress report 2024

The progress to date of the 2024 Service Plan was reviewed. The status and progress under each of the five goals were outlined and discussed. As of June, 23% of activities have been completed, 68% of were on target, 4% were subject to minor delays, and 5% had yet to be started.

7.2 2025 high-level business planning

The key priorities for the strategic goals under 2025 service plan were outlined.

* Ms Purcell joined the meeting.

8 RISK MANAGEMENT – PERIODIC RISK REGISTER REVIEW

The risk register was reviewed, and the updates were noted. No new risks were identified but minor amendments were noted to four existing risks. Following discussion amongst the Authority, it was agreed to update the risk register to reflect the potential risk levels in relation to headcount approval by the Department. There was no change to the risk management framework.

*The Operational Excellence manager left the meeting.

9 PROPOSED RENOVATION TO KEVIN O'MALLEY HOUSE

The proposed renovations to Kevin O'Malley House were outlined to the Authority. The budget and tender documents were reviewed and approved by the Audit and Risk Committee (ARC) at its meeting on 25 September. The HPRA's plans to increase hot desking to support the renovations was noted. The Authority adopted the proposal. The projected timeline for completion of the renovations is quarter one, 2025.

10 SODIUM VALPROATE

A further update on the work carried out to prepare for the Sodium Valproate inquiry was provided to the Authority. It was noted that a subgroup of Authority members has been created to review the planned HPRA submission documents. It was also noted that the regulatory systems statement with supporting documentation (one of the two primary statements), had been shared with the Chair. The Chair expressed confidence in the actions taken to date.

*Ms R. Purcell left the meeting.

11 COMMITTEE UPDATES

Statutory Committee	Last meeting date	Updates
Audit and Risk Committee (ARC)	25 September 2024	An update was provided by the ARC Chair following the meeting on 25 September at which the ARC reviewed: - the risk register - proposal for the renovation of Kevin O'Malley House Both were recommended to the Authority. The Authority was informed that the ARC meeting was also attended by a representative of the C&AG to present on the recent financial audit. Additional items considered by the ARC included the HPRA investment policy and headcount. The signed minutes from the 27 March ARC meeting were provided to the Authority.
Advisory Committee Veterinary Medicines (ACVM)	None since the last meeting	N/A
Advisory Committee Medical Devices (ACMD)	27 May 2024	The ACMD Chair provided an update on the report on the recent meeting of ACMD. Items highlighted to the Authority included ongoing efforts in relation to recruitment of new Committee members.
Advisory Committee Human Medicines (ACHM)	24 April 2024	The report was taken as read.

12 AOB

12.1 Authority appointments

The Chair updated the Authority members on the ongoing process of appointing a replacement for the outgoing Authority member, Dr Quinlan. It was noted that a number of highly qualified candidates had applied, and it is hoped that the newly appointed member will be in situ ahead of the November Authority meeting. Dr Collins and Professor Reilly confirmed their commitment to serving a second term on the Authority. The Chair and the secretary will liaise with the Department in relation to these re-appointments.

13 ANNUAL REPORTS

The 2023 HPRA Annual Report was provided for information and was taken as read. The 2023 Patient Forum Annual Report was approved.

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

- Health (Miscellaneous Provisions) Act 2024 (No. 23/2024)
- Medicinal Products (Prescription and Control of Supply) (Amendment) (No.4) Regulations 2024 (SI 458/2024)
- Veterinary Medicinal Products Regulations 2024 (SI 462/2024)
- Regulation (EU) 2024/1860 of the European Parliament and of the Council of 13 June 2024
- Regulation (EU) 2024/1938 of the European Parliament and of the Council of 13 June 2024 on standards of quality and safety for substances of human origin intended for human application and repealing Directives 2002/98/EC and 2004/23/EC

15 FINANCE ACCOUNTS – APRIL 2024 AND JULY 2024

The Authority noted the management accounts for April and July 2024.

16 LICENSING ACTIVITIES – TABLES OF LICENCES APPROVED

The Authority noted the tables provided specifying the authorisations approved by the HPRA Leadership Team during the period 26/04/2024 to 06/09/2024.