HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

Wednesday, 23 June 2022, 2:00 pm (hybrid meeting)
Report of the Authority

Chair	Mr M. Donnelly
Present	Dr D. Quinlan*, Dr P. Kilbane, Prof S. O'Kane, Prof R. Reilly*, Dr J. Collins*, Mr D. Holohan, Mr B. Jones*
In attendance	Dr L. Nolan (Chief Executive), Ms. R. Purcell** (Deputy Chief Executive)
Apologies	None
Minutes	Dr Karl Cogan (Executive Assistant)

* attended the meeting remotely
** attended for part of meeting

1 Declarations of interest/ Conflicts of Interest

Prof. S. O'Kane, Dr. P. Kilbane and Dr. J. Collins noted their conflicts as per the annual declarations received.

2 Authority Report

The report of the meeting of 11 May 2022 was adopted.

3 Health and Safety Update

There was nothing to report.

4 Chief Executives Update

Specific points discussed included:

Low Dose Codeine Preparations

The EMA's Pharmacovigilance Risk Assessment Committee (PRAC) adopted a new signal for renal tubular acidosis (RTA) and hypokalaemia associated with misuse of codeine ibuprofen containing products during its June meeting following a request for review of a potential signal by the HPRA. The HPRA is the lead member state for the investigation of this signal.

Medical Devices

An update was provided on the recent Employment, Social Policy, Health and Consumer Affairs Council configuration (EPSCO) meeting which had included an update from the European Commission on progress regarding the implementation of the Medical Devices Regulation. A number of member states, including Ireland, intervened to highlight key challenges facing the regulatory system at present, including notified body capacity, and emphasised the need for enhanced efforts to resolve outstanding issues. Further discussion is anticipated during the December EPSCO meeting.

An update was also provided on the on-going work at national level, and within the European regulatory network, focusing on system strengthening for medical devices.

Meeting with Secretary General of the Department of Health

The Chair and the Chief Executive updated Authority members on a recent meeting with the Secretary General of the Department of Health. The meeting provided an opportunity to discuss the HPRA's role in the broader public health system, its contribution to the national pandemic response, and its European and international role among other topics.

Communications Strategy

An update was provided on the on-going development of the HPRA's new communication strategy. The strategy is intended to support the delivery of communication-related activities and goals identified in the HPRA's Strategic Plan 2021-2025. The Authority will receive further updates once the strategy is finalised.

Future of Work

The Chief Executive reported that hybrid working continues to progress well across the organisation. An update was also provided on the approach that will be taken for evaluation of the impact and effectiveness of hybrid working for the organisation.

ICMRA Summit Meeting

An update was given on the on-going preparations for the International Coalition of Medicines Regulatory Authorities (ICMRA) Summit Meeting which the HPRA is hosting in Q4. The Authority indicated its support of the proposed approach and budget.

5 Performance Review Committee – Update from meeting (21 June)

The Chair provided an update concerning the Chief Executive's recent performance review highlighting that all key targets were achieved in 2021, and that the organisation is again well positioned to deliver on 2022 objectives.

6 Sodium Valproate

**The Deputy Chief Executive joined the meeting.*

An update on the on-going preparatory work for the sodium valproate inquiry was given.

**The Deputy Chief Executive left the meeting.*

7 Administrative Matters

7.1 Approach for September Authority Meeting

Authority members discussed an approach to the September meeting focusing on Board dynamics. It was agreed to host this session in the HPRA offices. The Chair and Chief Executive will finalise the final format of the session and update the members in advance.

7.2 Authority Vacancies

The current vacancy on the Authority has been advertised by the Public Appointments Service with a closing date for applications by mid-July.

8 AOB

The Chair proposed appointing Prof S. O'Kane to the Audit and Risk Committee, receiving full support from Authority members.

9 COVID-19 update

An update was provided in relation to developments concerning updated vaccine configurations to target SARS-CoV-2 variants, in addition to mechanisms to preserve critical medicines, and latest vaccine and therapeutic product safety information.

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

- Misuse of Drugs (Amendment) Regulations 2022 (SI 210/2022)
- Misuse of Drugs Act 1977 (Controlled Drugs) (Designation) Order 2022 (SI 211/2022)
- Misuse of Drugs (Prescription and Control of Supply of Cannabis for Medical Use) (Amendment) Regulations 2022 (SI 237/2022)
- In Vitro Diagnostic Medical Devices Regulations 2022 (SI 256/2022)
- European Union (National Research Ethics Committees For Performance Studies of In Vitro Diagnostic Medical Devices) Regulations 2022 (SI 257/2022)
- Medicinal Products (Safety Features on Packaging) Regulations 2022 (SI 270/2022)

11 Management Accounts April 2022

The Authority noted the management accounts for April 2022.

12 Licensing activities

The Authority noted the tables specifying the authorisations approved by the Management Committee during the period 06/05/2022 to 17/06/2022.