HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

Wednesday, 27 March 2024, 14.00 pm (hybrid meeting)
Report of the Authority

Chair	Mr M. Donnelly
Present	Prof S. O'Kane, Dr J. Collins**, Dr D. Quinlan, Dr F. Kiernan, Mr B. Jones, Prof R. Reilly, Mr D. Holohan, Dr P. Kilbane
In attendance	Dr L. Nolan, Chief Executive; Dr G. Power*, Director of Compliance; Ms S. Curran*, Director of Human Products Monitoring; Corporate Affairs Manager; Operational Excellence Manager*; Executive Assistant to the Chief Executive*
Apologies	-
Minutes	Ms K. Murphy, Secretary to the Committees

*attended for part of 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 the their annual declarations.

3 Report of the meeting 25 January 2024
The report of the meeting of 25 January 2024 was approved.

4 Health and safety
There was nothing to report.

5 Chief Executive's update
Specific points discussed included:

Access to medicines
The Authority was informed that oversight of the multi-stakeholder framework on medicines shortages remains a priority for the organisation. The Medicines Criticality Group (MCAG) established to focus on Winter seasonal illness had been very effective over the recent months. Meeting frequency is now being reduced as the season has passed. Monitoring of the situation will remain on-going. An update was provided on a number of potential shortages.

Regarding shortages of veterinary medicines, it was noted that the Department of Agriculture, Food and the Marine was the supervisory authority for veterinary wholesalers. The matter was discussed by the Advisory Committee for Veterinary Medicines (ACVM) at its recent meeting at which members commended the HPRA for its work in this area. Efforts to improve transparency in this area include the planned publication of veterinary medicines shortages which was welcomed.

Aesthetic products
The recent RTE Investigates broadcast on botulinum toxin on 4 March was discussed. The communication strategy adopted by the organisation was noted. It was clarified that the Authority are notified in advance on matters of this nature.

Strategic workforce planning
In January 2024, the HPRA submitted a Strategic Workforce Plan to the Department of Health. The document outlines the resource requirements of the organisation for a two-year period.

Reorganisation of the HR and Change Department
Further information was provided to the Authority on the formal reorganisation of the Human Resources and Development (HRD) department. The reorganisation, aligns with the HPRA's People Strategy.

Website redevelopment project
The timeline for completion of the website project remains on track for quarter four of 2024. The project is progressing well, and initial design concepts have been reviewed by the HPRA Leadership Team. The design concepts will be shared with the Authority during its next update. Routine testing of the cybersecurity of the current website is ongoing and consideration will be given to delivering security training to Authority members over the coming months.

6 IBTS report

The HPRA's 26th annual report to the Minister for Health on the Irish Blood Transfusion Service, for the year 2022, was discussed. The report was approved by the Authority.

7 Compliance update

*Dr G. Power joined the meeting

An overview of the HPRA's Compliance Department was provided. The overview included the Departments' portfolio, the challenges and opportunities it faces, national and international engagement being undertaken, as well as focus areas for 2024.

Some of the key projects for the year which were highlighted include working closely with the current President of the European Council, Belgium, to address medicines shortages across the network, commencing preparations for the HMA/EMA Joint Audit Programme (JAP), as well as work to be undertaken by the new shortages and borderline classification team.

The Authority was informed that as part of the Department's good manufacturing practice (GMP) and good clinical practice (GCP) activities, colleagues are required to undertake inspections in third countries on behalf of the European Medicines Agency (EMA). Compliance colleagues are also involved in activities at European Commission level and with the global Pharmaceutical Inspection Co-operation Scheme (PIC/S). It was also noted that to assist the Department of Health nationally, the HPRA has offered to lead in the establishment of a national forum on medicines availability.

*Dr G. Power left the meeting

8 Sodium Valproate pregnancy prevention programme

*Ms S. Curran joined the meeting

An overview was given in relation to sodium valproate containing medicines, the EMA referrals and risk monitoring measures including the current pregnancy prevention programme. The Authority noted the comprehensive nature of the HPRA's on-going work in this area.

The recent publication by the Department of Health of an appointment notice for the Chair of a non-statutory inquiry into the historical licensing and use of sodium valproate in women of childbearing potential in the state was noted and welcomed by the Authority and the Executive.

*Ms S. Curran left the meeting

9 HPRA Service Plan 2023: Outturn

*The Operational Excellence Manager and the Executive Assistant to the Chief Executive joined the meeting

An overview was provided on the 2023 Service Plan. The various actions of the service plan under the HPRA's five strategic goals were outlined. It was noted that by the end of 2023, 88 % of actions had been completed,15 actions were ongoing while two were not started due to external factors. Of the two actions not achieved, one was due to the delay in implementing the new Veterinary Regulation 2019/6 while the other cannot be implemented until the EMA finalises its digital application (dataset integration) forms.

*The Operational Excellence Manager left the meeting

10 HPRA Strategic Plan: 2023 Outturn

An update was given on the progress of year three of the strategic plan. Specific action items from each of the five goals were outlined. It was noted that the mid-term review of the strategic plan, which was undertaken last year involving input from Authority members, had reconfirmed the goals and objectives. A number of minor modifications had been incorporated into the 2024 service plan as result of the review. Emerging issues which could potentially impact the strategic plan were identified.

*The Executive Assistant to the Chief Executive left the meeting

11 Risk register review: Risk management report

The Audit and Risk Committee (ARC) reviewed the Risk Register at its meeting of 27 March 2024 and recommended the register to the Authority for approval. The Authority weas informed that updates to the register included the reduction of the risk relating to ICT infrastructure following recent updates to the disaster recovery plans. The Authority approved the risk register.

12 National Concert Hall grant

The Authority considered and approved support for the National Concert Hall programme which provides music in healthcare settings.

13 Committee updates

Statutory Committee	Last Meeting Date	Updates
Audit and Risk Committee (ARC)	27 March 2024	A verbal update was provided by the ARC Chair following the meeting on 27 March. The update included the positive outcome of the latest internal audit conducted by Mazers in relation to ICT disaster recovery. The ARC also reviewed the 2024 Corporate Procurement Plan and the System of Internal Controls for the year ended 31 December 2023. Following a recommendation by the Committee, both were reviewed and approved by the Authority.
Advisory Committee Veterinary Medicines (ACVM)	06 March 2024	The ACVM Chair provided an update on the recent meeting of the Committee. Items highlighted to the Authority include shortages of veterinary medicines, the addition of new members to the Committee, and the planned requirement under the new veterinary medicines regulation for antibiotic usage data to be submitted by Member States.
Advisory Committee Medical Devices (ACMD)	27 November 2023	The ACMD Chair provided an update on the recent meeting of the ACMD. The Chair highlighted difficulties encountered in relation to recruiting members to the Committee.
Advisory Committee Human Medicines (ACHM)	None since last meeting	N/A

14 AOB

Public relations

It was noted that a tender for public relations support, incorporating crisis communication support, will be issued shortly.

PWC Business Post Sustainable Business Awards 2024

The Authority was informed of the recent shortlisting of the HPRA in the category of best sustainable commercial or State body at the PWC Business Post Sustainable Business Awards. While the HPRA did not win, the PWC acknowledged the outstanding energy reductions achieved by the organisation. This was driven entirely by an internal voluntary green team committee (ENSUS) demonstrating how smaller, non-commercial organisations can achieve real sustainability success. The HPRA is currently six years ahead of public sector

energy related targets which require the organisation to have achieved 51% of the energy related targets by 2030. The HPRA has already achieved 69.1% of these targets.

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

- Misuse of Drugs (Amendment) Regulations 2024 (SI 71/2024)
- Medicinal Products (Prescription and Control of Supply) (Amendment) Regulations 2024 (SI 72/2024)
- Medicinal Products (Prescription and Control of Supply) (Amendment) (No 2) Regulations 2024 (SI 73/2024)
- Human Tissues (Transplantation, Post-Mortem, Anatomical Examination and Public Display) Act 2024) (No. 5/2024)

16 Finance accounts – December 2023 and January 2024

The Authority noted the management accounts for December 2023 and January 2024.

17 Licensing activities – Tables of licences approved

The Authority noted the tables provided specifying the authorisations approved by the HPRA Leadership Team during the period 12/01/2024 to 08/03/2024.

18 Authority schedule of matters 2024

The Authority noted the 2024 schedule of matters.

19 Closed session of the Authority

A closed session of the Authority was held after the Authority meeting. The closed session was attended by members of the Authority only.