HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

Wednesday, 27 September 2023, 1.30 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
In attendance	Dr L. Nolan, Chief Executive; Dr J.G. Beechinor*, Director of Veterinary Sciences; Ms. R. Purcell*, Deputy Chief Executive; Quality Manager*
Apologies	Dr P. Kilbane
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 noted conflicts as per the annual declarations received.

3 Report of the meeting 24 May 2023
The report of the meeting of 24 May was approved.

4 Health and safety
Update of health and safety statement
The updated health and safety statement was provided to the Authority and the primary changes were highlighted.

5 Chief Executive's update
Specific points discussed included:

Medicines availability
The Authority members were informed that the HPRA had met with the Minister for Health in relation to shortages. The work on the website giving information on shortages and the ongoing detailed work in relation to particular shortages were outlined. Developments to enhance medicines supply chain resilience and more effectively manage acute shortage situations were also discussed. A further update will be provided to the Authority at the next meeting.

Ozempic
As part of ongoing efforts to manage the supply of Ozempic nationally, the HPRA convened cross-agency meetings with stakeholders including the Department of Health, the HSE, the Pharmaceutical Society of Ireland, and the Medical Council. A joint communication relating to the supply interruption was issued.

Expert taskforce to support the expansion of the role of pharmacists in Ireland
On the 23 July 2023, the Minister for Health established an expert taskforce to support the expansion of the role of pharmacists in Ireland. The taskforce will consider how the role of

pharmacists can be enhanced to assist with GP and hospital capacity. The HPRA was requested to join the taskforce. As part of the first phase of this initiative, the taskforce will consider the extension of prescriptions for a range of medicines while prescribing by pharmacists will be considered during the second phase. The Authority welcomed the establishment of the taskforce and the HPRA's involvement. The Authority also supported a request by the taskforce to engage with the HPRA's patient forum while recognising that the views expressed by the forum to the taskforce are independent of the HPRA.

Website update

An update on the new website was provided to the Authority. The project continues to progress well. As part of the project, content writing and document migration guidelines are being established and the governance of the project will be overseen by the HPRA leadership team. To ensure that the website will meet the needs of users, a stakeholder analysis is being conducted.

Windsor framework

The Windsor framework is due to come into effect on 1 January 2025 at which point joint medicines packs between Ireland and the UK will no longer be possible. As part of ongoing preparations, the HPRA is focusing on both nationally authorised medicines as well as those approved via the centralised, European system. The HPRA is engaging with manufacturers as well as the EMA and the UK's MHRA.

Childrens Hospital Ireland review

An update was provided in relation to issues that have arisen at Children's Health Ireland (CHI) Temple Street. It was noted that the compression springs used in certain surgeries were never intended to be used as a medical device and therefore the description of these springs as unauthorised medical devices is incorrect. The Authority was reminded of the regulatory path of medical devices which requires that medical devices meet requirements set out in the Medical Device Regulation (EU) 2017/745 (MDR). Before a device can be placed on the market it is required to be assessed and issued a CE certificate by a notified body. The use of non-CE marked devices is strictly controlled and is limited to use in particular circumstances such as in a clinical investigation.

*Dr D. Quinlan left the meeting

6 Performance Review Committee

The Authority was informed of the Performance Review Committees (PRC) meeting with the Chief Executive and outcomes. Work remains ongoing regarding succession planning for senior roles within the organisation. This will continue to be an area of on-going focus. The PRC expressed its satisfaction with the update.

7 Veterinary regulations

*Dr J.G. Beechinor joined the meeting

The Director of Veterinary Sciences provided an overview of the HPRA Veterinary Science Department as well as the evolving regulatory landscape for veterinary medicines. The departments' primary areas of focus were outlined including stakeholder engagement. The organisation's consistently strong performance within the European regulatory network

was highlighted with the HPRA consistently in the top three EU countries across a range of outputs. The Authority was also informed that the department has a leading role in pharmacovigilance monitoring in the EU.

Possible challenges were discussed such as the review of EMA fees and the impact Brexit may have on joint labelling for veterinary medicines. The potential changes as a result of the EU Regulation 2019/6 were highlighted and included the continued development of the union product database which acts as a centralised repository and management system for veterinary product related information. The revision and expansion of national legislation to support the regulation were also outlined.

As part of next steps for the department, an external consultant has been engaged to assist with developing a new veterinary science strategy. Once the report has been finalised it will be provided to the Authority. The Authority commended veterinary colleagues for their work undertaken to date in particular their involvement and contribution at EU level.

*Dr J.G. Beechnoir left the meeting

8 Sodium valproate

*Ms R. Purcell and Dr D. Quinlan joined the meeting

An update on the work carried out to prepare for the Sodium Valproate inquiry was provided to the Authority.

9 Building development

A proposal to install solar panels and a decentralised water heating, and to carry out a deep service of the air conditioning and air handling systems, was approved. It was noted that while the air conditioning systems are close to end of life, it was agreed that this project would be postponed until we consider further the use of the building and the positioning of air conditioning units to future proof the office use. All the projects will help with the reduction of greenhouse gasses.

*Ms R. Purcell left the meeting

10 Strategic plan mid-term review

*The Quality Manager joined the meeting

The action areas identified from the strategic plan mid-term review were presented. Thanks were extended to the participating Authority members who undertook the review in conjunction with Directors and other HPRA colleagues. As part of the review, two actions were removed, three new actions were added, while nine actions were reworded for clarity. Also as part of the review, it was agreed that the next HPRA strategic plan will be shortened to cover a three-year period.

11 Service planning

H1 2023 Report

An overview of the outturn of the 2023 service plan was provided detailing the status of activities under each goal and objective, and comparing these against the last two years.

2024 high-level planning
An update was provided on the ongoing service planning for 2024. The full-service plan for 2024 will be presented at the November Authority meeting.

12 Risk management

Risk register review
The risk register was reviewed, and the updates were noted. There was no change to the risk management framework.

*The Quality Manager left the meeting

13 Succession planning

Thanks were extended to Authority members for their completion of a recently circulated Authority skills survey. A draft skills competence list has been completed from responses and potential opportunities have been identified for consideration in 2024 in line with Authority vacancies. Further discussion will take place during forth-coming meetings.

14 Committee updates

Statutory Committee	Last Meeting Date	Updates
Advisory Committee Medical Devices (ACMD)	14 June 2023	The report was taken as read.
Advisory Committee Veterinary Medicines (ACVM)	1 August 2023	The ACVM Chair provided an update on the report on the recent meeting of the ACVM.
Audit and Risk Committee (ARC)	15 September 2023	The ARC Chair provided an update on the report on the recent meeting of the ARC. The outcome of an internal review by Mazars on the internal financial controls was outlined noting that only two low-risk matters were identified.
Advisory Committee Human Medicines (ACHM)	None since last meeting	N/A

15 AOB

There was nothing to report.

16 2024 Authority meeting dates

The proposed 2024 Authority meeting dates were reviewed and confirmed.

17 2023 Authority calendar

The Authority calendar to the end of the year was noted.

18 Annual reports

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

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

- Medicinal Products (Prescription and Control of Supply) (Amendment) (No 3) Regulations 2023 (SI 238/2023)
- Medicinal Products (Prescription and Control of Supply) (Amendment) (No 4) Regulations 2023 (SI 284/2023)
- Veterinary Medicinal Products, Medicated Feed and Fertilisers Regulation Act 2023 (No. 21 of 2023)

20 Finance accounts – February and March 2023

The Authority noted the management accounts for April, May, June, and July 2023.

21 Licensing activities – Tables of licences approved

The Authority noted the availability of the tables specifying the authorisations approved by the HPRA Leadership Team during the period 19/05/2023 to 08/09/2023.