HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

Wednesday, 25 January 2024, 9.00 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; Ms. R. Purcell*, Deputy Chief Executive; Corporate Affairs Manager; HR consultant*
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 and Dr P. Kilbane noted conflicts as per the annual declarations received. Dr J. Collins declared a new interest in relation to his role as vice-president of the Federation of European Equine Veterinary Associations (FEEVA).

3 Report of the meeting 29 November 2023
The report of the meeting of 29 November 2023 was approved.

4 Health and safety
There was nothing to report.

5 Chief Executive's update
Specific points discussed included:

Sodium valproate: new precautionary measures for men
An update was provided to the Authority on the recent Pharmacovigilance Risk Assessment Committee (PRAC) review of data on paternal exposure to valproate. The review recommended precautionary measures for the treatment of male patients to address the potential risk of neurodevelopmental disorders in children whose fathers are treated with valproate.

It was noted that the study data on male patients had limitations. The PRAC could therefore not establish whether the increased occurrence of neurodevelopmental disorders suggested by the study was due to valproate use. In addition, the study was not large enough to identify which types of disorders children could be at increased risk of developing. Nonetheless, the Committee considered precautionary measures were warranted to inform patients and healthcare professionals.

The Authority was updated on the HPRA's ongoing consultation with patient groups and healthcare professionals in Ireland on this matter.

Medicines accessibility
The Authority was informed that the Medicines Criticality Group (MCAG), convened to address availability issues over the Winter season, continues to meet on a regular basis. An update was provided on the work of this group. An update was also given on recent availability issues with medicines used to treat ADHD. While stocks of affected active ingredients remain available, the HPRA plans to issue communications via its website to stakeholders highlighting the current availability of ADHD medications as well as suitable alternatives.

Medical devices update
The European Commission's proposal to defer the implementation of the *In Vitro* Medical Devices Regulation (IVDR) until 2027 was discussed. The HPRA continues to support calls for the Commission to require manufacturers to notify national competent authorities in instances where they do not plan to transition to assist with monitoring and ensuring availability of devices. The HPRA also continues to support a review of how the implementation of the Regulation can be accelerated.

People Strategy and launch of HR & Change Department Strategy
An overview was provided on the launch of the HPRA's HR and Change department strategy. The strategy will support the HPRA's current People Strategy and directly maps the four pillars contained in this strategy to the career trajectories of colleagues. A further update on the new strategy will be provided to the Authority at a later date.

HPRA Communication and Stakeholder Engagement
An update was given on developments to enhance the organisation's approach to communications and engagement. Stakeholder leads have been appointed to a number of departments internally to assist the organisation in driving proactive stakeholder communications, engagement, and outreach. The continued recruitment of key personnel to the organisation to support the strategy remains a vital component of the review and efforts in this area are ongoing. Work on the website redesign is ongoing and an update on this will be provided at a future meeting of the Authority.

6 Windsor framework
*Ms R. Purcell joined the meeting

An update was provided on Brexit and the considerable work undertaken by the HPRA and marketing authorisation holders (MAHs) to date to comply with requirements. The implications of the Windsor Framework, agreed in March 2023, was outlined noting that these were not part of the original Brexit requirements for human medicines. Under this framework, medicines with joint IE/UK labels will no longer be feasible. From 1 January 2025, medicines placed on the UK market will carry the words "UK only" and may not carry the safety barcode required by the Falsified Medicines Directive.

The possible implications of the impact of the Windsor Framework on the supply of medicines in Ireland was discussed. The Authority were assured that the HPRA is taking every effort to encourage companies to minimise any possible disruption to the supply of medicines in Ireland. To assist in mitigating any possible impact, the HPRA contacted all national MAHs and the EMA issued similar communications to MAHs of centralised

products. It was noted that neither medical devices nor veterinary medicines are subject to the Windsor Framework.

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

7 Board review

The ongoing review of the Authority was discussed.

8 Board succession planning

*HR consultant joined the meeting

The objectives of the annual succession planning of the Authority were outlined. One of the primary objectives is ensuring that the levels of expertise, knowledge, skills, and behaviours required by the Authority are in place. Other objectives include the ongoing development of members as well as the proactive management of Authority member's tenure to ensure the acquisition and retention of the optimum skills mix.

The importance of the skills and experience required for incoming members was discussed noting that three members of the Authority must also be in a position to chair the relevant technical subcommittees. The changing nature of the regulatory landscape and the need to apply horizon scanning when considering the required skills and experience of future appointees was highlighted. The possible expansion of AI and data management, changes in innovation, and the organisations strategic emphasis on strengthening health system partnerships, were all outlined as areas also requiring consideration for future appointments.

*Dr D. Quinlan rejoined the meeting

In addition, the need for future appointments to take into consideration the gender balance on the Authority was noted.

*HR consultant left the meeting

9 Committee updates

Statutory Committee	Last Meeting Date	Updates
Audit and Risk Committee (ARC)	15 September 2023	The ARC meeting report of 15 September 2023 was taken as read. The 2023 ARC annual report was provided to members. The ARC Chair thanked the members of the committee for their continued high levels of engagement. Work is underway to allow Authority members to access all the ARC meeting documentation going forward.

		The first meeting date for the ARC in 2024 was noted.
Advisory Committee Veterinary Medicines (ACVM)	None since the last meeting	The first meeting date for the ACVM in 2024 was noted.
Advisory Committee Medical Devices (ACMD)	27 November 2023	The ACMD Chair report from the 27 November meeting will be provided to members for consideration at the next Authority meeting. The first meeting date for the ACMD in 2024 was noted.
Advisory Committee Human Medicines (ACHM)	None since last meeting	The first meeting date for the ACHM in 2024 was noted.

10 AOB

There was nothing to report.

11 2024 Authority meeting dates

The 2024 Authority meeting dates were re-circulated to members for ease of reference following changes to some of the dates.

12 DoIs and Ethics in Public Office Forms/Conflicts of interest

Members were reminded to submit their declarations of interest (DoIs) and ethics in public office forms as soon as possible if not already returned. Thanks were extended to those members who had already submitted their forms.

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

- Medicinal Products (Prescription and Control of Supply) (Amendment) (No 6) Regulations 2023(SI 451/2023)
- Medicinal Products (Prescription and Control of Supply) (Amendment) (No 7) Regulations 2023 (SI 584/2023)
- European Union (National Research Ethics Committees for Clinical Investigations of Medical Devices) Regulations 2023 (SI 671/2023)
- Health Products Regulatory Authority (Fees) Regulations 2023 (SI 697/2023)
- European Union (Clinical Trials on Medicinal Products for Human Use) (Amendment) Regulations 2024 (SI 3/2024)

14 Finance accounts – October and November 2023

The Authority noted the management accounts for October and November 2023.

15 Licensing activities – Tables of licences approved

The Authority noted the tables provided specifying the authorisations approved by the HPRA Leadership Team during the period 17/11/2023 to 05/01/2024.

16 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.