HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

Wednesday, 05 April 2023, 9.30 am (hybrid meeting)
Report of the Authority

Chair	Mr M. Donnelly
Present	Dr P. Kilbane, Prof S. O'Kane**, Dr J. Collins, Mr D. Holohan, Dr D. Quinlan**, Dr F. Kiernan**, Mr B. Jones*
In attendance	Dr L. Nolan, Chief Executive (CE), Mr S. d'Art*, Director of ICT and Business Services, Ms G. Power*, Compliance Director, Quality Manager*, Ms E. Stuart*, Director of Human Resources and Change.
Apologies	Prof R. Reilly
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 their conflicts as per the annual declarations received.

3 Report of the meeting January 2023
The report of the meeting of 19 January was approved.

4 Health and Safety Update
There was nothing to report.

5 Chief Executive's update
Specific points discussed included:

Engagement with IBTS
An update was given on ongoing engagement between the HPRA and the National Haemovigilance Office (NHO) and on future planned developments. This includes an IT system to facilitate simultaneous reporting to both organisations, which is expected by year-end. Currently, the HPRA receives real-time reports from the NHO via email. A meeting between the Department of Health, the HPRA, and the NHO is planned for later in the year.

Impacts of the Windsor Framework
The impact of the Windsor Framework was discussed. Under the framework, the safety feature required under EU law will no longer be permitted on the outer packaging / labels for medicines in Northern Ireland (NI). In addition, it will be a requirement that these medicines carry the wording "UK only". Separate packaging will therefore be required for the UK meaning joint IE/UK packaging will not be possible. Consideration is to be given to products supplied to the Irish market by small UK manufacturers. Broader engagement with marketing authorisation holders is also planned over the coming months on the issue of separate packaging and generally on the expiry of the existing derogations at the end of

2024. It was also noted that under the framework the medicines authorised by the Commission on advice from the EMA will no longer be permitted to be on the NI market. Such medicines will be authorised by the UK competent authority. At present, veterinary products are not covered by the Windsor framework.

Staff Engagement Survey
The Authority was informed that the staff engagement survey, undertaken in December 2022, indicated that overall staff sentiment and positivity were favourable.

Medical Devices – Implementation of Regulations 2017/745 (MDR) and 2017/746 (IVDR)
The publication by the European Commission of Regulation 2023/607 covering amendment to the transition provisions (Article 120) of the MDR was noted. The development of the Regulation was significantly influenced by calls from Member States, including Ireland, for the need of an additional transitional period due to lack of capacity within the notified bodies network. It was noted that the HPRA had played a leadership role within the Heads of Medicines Agency Core Group for Medical Devices in advocating for this approach.

It was also outlined that the amendment to the transition provisions, while necessary, do not address underlying challenges with the broader implementation of MDR and IVDR. Focus on system strengthening is a key priority for the HPRA and we continue to work to influence this at national and European level.

*Ms G. Power joined the meeting

Winter Surge and Medicine Supply Update
An update was provided in relation to notified medicines shortages. As part of the update, it was noted that a stakeholder review of the Medicinal Product Shortages Framework was conducted in November 2022 and published on the HPRA website.

Potential shortages are notified to the HPRA. The HPRA will then assess the potential impact of each shortage. Shortages deemed to be of medium and high risk are published on the HPRA website along with expected date that supply will be resumed. The HPRA engages closely with the marketing authorisation holders (MAH) in sourcing an alternative supply as well as engaging with other suppliers of the medicinal product. Where a generic or an alternative source of the medicine cannot be identified, the HPRA engages closely with its health system partners.

The HPRA are satisfied that the way in which shortages are managed optimises patient care and accessibility despite the challenges presented by each individual case. However, given the media coverage in recent months, further work on communication and engagement with stakeholders is being undertaken.

*Ms G. Power left the meeting

6 Website Development Project
*Mr S. d'Art joined the meeting

As part of the update on the website development project, the background and objectives of the rebuild were outlined. Increased stakeholder accessibility and compliance with accessibility Directives were identified as key objectives.

Following the recent tender process, a developer has been appointed to complete the build. With the developer now onboard, the detailed planning for the project will be finalised.

The communications team have completed a review of each departments current content approach and practices and have completed a HPRA website style guide that will be made available to all colleagues. Training in writing for a website is also being delivered to nominated colleagues in each section.

The governance structure was outlined with the HPRA leadership team having overall responsibility for the direction of the project and its alignment with organisation values. A suggestion that the project involve the HPRA Patient Forum was welcomed, and the project will be brought back to the Authority at a later date for further discussion.

*Mr S. d'Art left the meeting

7 Service Plan

*The quality manager joined the meeting

An overview was provided on the 2022 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 2022, 79% of the actions listed had been fully achieved, with 20% partially achieved while 1% was not achieved. This compares favourably with 2021 where the number of actions achieved was lower while the number of actions not achieved was higher. Of the 1% not achieved, it was noted that there were extenuating circumstances such as the implementation of legislation or guidelines. The improvement in performance between 2021 and 2022 can be attributed to the planned actions being more focused, and achievable within the timeframe as well as the integration of the service plan with department plans, and individual personal development plans. The impact of unforeseen work on internal capacity in some areas was also highlighted.

2022 Service volumes were reviewed and were 3% behind target. It was noted, however, that overall this was not a cause for concern.

8 HPRA Strategic Plan:

<u>2022 Outturn</u>

An update was given on progress with year two of the Strategic Plan. Emphasis was placed on Strategic Goal 1, Health system partnerships, and Strategic Goal 3, Communication and Engagement. Emerging issues which could potentially impact the strategic plan were identified.

<u>Interim review of strategy</u>

The objectives for the proposal of a midterm review of the strategic plan were discussed. The review is planned to commence in June and will focus on the objectives and outcomes listed under each of the five goals. Following a call for members to be involved in the review, three members of the Authority volunteered to participate, and the Chair extended his

thanks to these members. The report from the review is expected to be available to the Authority later in the year. As part of the review, consideration will also be given to the next strategic plan which will cover a three-year period as previously requested by the Authority.

9 Risk Register Review

The Audit and Risk Committee (ARC) reviewed the Risk Register and recommended the register to the Authority. The Authority were informed that updates to the register included the addition of risk owners, a risk appetite, as well as reference to the agreement with the NHO. The Authority commended the register for being both thorough and well presented and approved the risk register.

*The quality manager left the meeting

10 HPRA People Strategy

*Ms E. Stuart joined the meeting

Presentation

A presentation on the HPRA People Strategy was delivered to the Authority. Although the strategy was developed by the HR and Change section, it is being owned by the leadership team and the organisation as a whole. The development of the strategy included extensive staff engagement which was conducted through workshops. This was also supported through the conduct of external research.

The strategy recognises the importance of HPRA colleagues as being key to the organisations success and aims to support colleagues in their development. The strategy will assist in creating a positive work experience for all HPRA colleagues while also helping the organisation to deliver on its strategic goals. The strategy comprises four pillars: purpose, growth, belonging, and wellbeing, all of which are interconnected and closely linked to the vision, mission, and values set out in the strategic plan. The strategy emphasises a collective sense of purpose and the role all colleagues have in contributing to the success of the organisation.

*Mr B. Jones left the meeting

The need for the organisation to grow and foster a culture of high performance was discussed. Further work remains ongoing in the area of succession planning while work is planned in relation to increasing career progression and retention. The importance of fostering a sense of belonging amongst colleagues, especially post Covid-19 was emphasised as was the importance of diversity, equality, inclusion, and fairness. Work undertaken by the Wellbeing and the Social Committees as well as the ENSUS team were highlighted and commended.

The Strategy was launched on the 22 February with an in-person, all staff event which was the first of its kind since Covid-19. The Strategy was delivered to colleagues by members of the HLT to reflect the shared ownership. An external speaker, Bernard Jackman, attended the event and gave a talk on high performance which was closely aligned to the HPRA's four pillars. The Authority congratulated Ms Stuart on the Strategy and requested an update towards the end of the year.

*Ms E. Stuart left the meeting.

11 National Concert Hall Grant

The Authority considered and approved support for the National Concert Hall programme of music in health care settings.

12 Authority Self-Evaluation 2022

The results of the Authority self-evaluation were taken as read. Thanks were extended to the Authority members for completing the evaluation form which was circulated in December 2022.

13 Committee updates

Statutory Committee	Last Meeting Date	Updates
Audit and Risk Committee (ARC)	9 March 2023	Corporate Procurement Plan and Statement of Internal Control: The ARC reviewed the Corporate Procurement Plan and Statement of Internal Control and recommended it for review by the Authority. They were approved by the Authority via written procedure ahead of the meeting.
Advisory Committee Veterinary Medicines (ACVM)	29 March 2023	The ACVM Chair provided an update on the recent meeting of the ACVM.
Advisory Committee Medical Devices (ACMD)	None since last meeting	N/A
Advisory Committee Human Medicines (ACHM)	None since last meeting	N/A

14 AOB

There was nothing to report.

15 2023 Authority Calendar

The Authority calendar for the upcoming year was noted. There was a discussion regarding the revised date for the Authority away day and work continues in this regard.

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

- Health Products Regulatory Authority (Fees) Regulations 2022 (SI 679/2022)
- Misuse of Drugs (Prescription and Control of Supply of Cannabis for Medical Use) (Amendment) Regulations 2023 (SI 5/2023)
- Medicinal Products (Prescription and Control of Supply) (Amendment) Regulations 2023 (SI 11/2023)
- Medicinal Products (Prescription and Control of Supply) (Amendment) (No. 2) Regulations 2023 (SI 105/2023)

17 Finance Accounts – December 2022 and January 2022

The Authority noted the management accounts for December 2022 and January 2023.

18 Licensing Activities – Tables of Licences Approved:

The Authority noted the availability of the tables specifying the authorisations approved by the HLT during the period 20/01/2023 to 24/03/2023.