HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

Thursday, 19 January 2023, 2:00 pm (hybrid meeting)
Report of the Authority

Chair	Mr M. Donnelly
Present	Dr P. Kilbane, Prof S. O'Kane, Prof R. Reilly, Dr J. Collins, Mr D. Holohan, Dr D. Quinlan, Dr F. Kiernan
In attendance	Dr L. Nolan, Chief Executive (CE), Ms. R. Purcell*, Deputy Chief Executive, [redacted], Scientific Affairs Manager, Mr S. d'Art, Director of ICT and Business Services, [redacted], Medicine Shortages and Borderline Classification Manager, Ms G. Power, Compliance Director.
Apologies	Mr B. Jones
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 first Authority meeting of 2023.

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 December 2022
The report of the meeting of 7 December 2022 was further amended and approved.

As a matter arising from the report, an update was provided to the Authority on resources in relation to the six priority areas of the Service Plan. The Authority was informed that a 15% increase in resources is expected between 2022 and 2024 to allow for extra resources to be assigned to these areas as may be required.

4 Health and Safety Update
There was nothing to report.

5 Chief Executive's update
Specific points discussed included:

<u>COVID-19 Pandemic</u>
The Authority members agreed to remove COVID-19 as a standing item in the Chief Executive's update which is in line with the approach taken by the European Medicines Agency). Innovation in the area will be reported as required.

<u>Extension of Brexit Exemptions for Veterinary Medicines</u>
Following an update provided to the Authority at the meeting of 7 December 2022, the European Commission subsequently confirmed the extension of exemptions in relation to veterinary medicines for the Irish market. The work undertaken by colleagues in the Veterinary department with regard to this matter was commended.

Website Development Project
The Authority were apprised of the tender application process for the website development project which has now closed. A further update on this matter will be provided at the Authority meeting in March.

EU Fee Regulation
It was noted that discussion has commenced within the European Council on the proposed European Union (EU) fee Regulation.

6 Performance Review Committee

The Authority was informed that the Performance Review Committee (PRC) had met with the Chief Executive whose ongoing contribution to the organisation was commended.

The importance of succession planning over the upcoming years for the organisation was emphasised as was the increased role that the Authority will assume in this regard. An update on succession planning will be presented to the Authority by the PRC over the coming months.

7 Antibiotic Supply

*** [redacted] and *Ms G. Power joined the meeting

The update provided to the Authority members on the current supply of antibiotic medication ahead of the meeting was taken as read. The Authority was informed that the HPRA attended a meeting of the Medicines Criticality Group, which was recently reconvened by the Department of Health. It was noted that there had been a surge in demand for paediatric medication, especially antipyretic medication such as Calpol. However, supply across most products in this category had begun to increase with additional supply expected to be available over the coming weeks.

Provision of information on medicines availability to assist both healthcare professionals and patients was discussed. During the current circumstances, the shortages section of the HPRA website has been updated to provide specific information targeted at healthcare professionals to assist in determining the availability of supply. The HPRA and the Antimicrobial Resistance and Infection Control team continue to meet daily, and a stakeholder group meeting is planned to be held by the Department on 20 January.

The ongoing supply and demand for semaglutide, and the role of off label use was raised by the Authority.. The EU has convened a criticality group to review the issue, and e the HPRA has been in contact with the HSE to discuss this. It was noted that the company has increased production to meet the rising demands. A recent analysis undertaken by the HSE indicated that Ireland's experience with this was similar to most other Member States.

*** [redacted] and *Ms G. Power left the meeting

8 Update on HPRA Innovation Activities

* [redacted] joined the meeting

A presentation on the innovation activities of the HPRA was provided to the Authority. The HPRA's innovation office was created in 2016 and engages with researchers to provide

support on innovation throughout both the process to market and beyond. It was highlighted that supporting innovation represents a cornerstone of the organisation's strategy. The office is closely modelled on innovation offices in other competent authorities and acts as a gateway for submitting innovation queries to the organisation.

The Authority queried the resourcing levels required to support the activities of the innovation office and was informed that ongoing consideration is being given to internal succession planning and that a 10% uplift in recruitment has occurred in the key areas. In response to a query on the office's ability to stay abreast of emerging areas, it was outlined that this was made possible via a number of expert colleagues within the organisation as well as other colleagues sitting on the Committee for Advanced Therapies. In response to what further steps could be taken to enhance the organisation's role at national, EU and international level it was noted that HPRA's role as co-chair of the EU innovation network and co-leaders of the ICMRA innovation project ensures that the HPRA is well placed to further develop our innovation strategy.

The Chair and members of the Authority thanked [redacted] for all the work undertaken by the Innovation Office.

*[redacted] left the meeting

9 Update on Cybersecurity Enhancements

*Mr S. d'Art joined the meeting

An update on cybersecurity enhancements was presented to the Authority. The approach was welcomed by the Authority as was the emphasis placed on staff training, It was agreed that the Authority would be included in future training initiatives.

*Mr S. d'Art left the meeting

10 Terms of Reference for Authority and Management Committee - Editorial Amendments

It was outlined that a change in title had been proposed internally to update the Management Committee to the HPRA Leadership Team (HLT). The proposal stemmed from the expansion of the work which is now undertaken by the Management Committee. The Terms of Reference for both the Authority and Management Committee were updated to reflect this name change. It was also noted that other administrative changes had been undertaken. The Authority agreed the proposed updates.

11 Committee updates

Statutory Committee	Last Meeting Date	Updates
Audit and Risk Committee (ARC)	None since last meeting	The ARC annual report was provided to the Authority. The first meeting date for 2023 was also provided.

Advisory Committee Veterinary Medicines (ACVM)	None since last meeting	The first meeting date for 2023 was provided.
Advisory Committee Medical Devices (ACMD)	None since last meeting	The first meeting date for 2023 is pending.
Advisory Committee Human Medicines (ACHM)	None since last meeting	The first meeting date for 2023 was provided.
Performance Review Committee	19 January 2023	Discussed earlier in the meeting- noted under item 6 above.

12 Supplemental Mandate-Approved List of Signatories

The supplemental mandate to update the approved list of signatories was signed by the Chair and the Chief Executive at the meeting.

13 AOB

Secretary to the Committees

It was officially noted that Ms. K. Murphy had assumed the role of Secretary to the Committees as well as the Authority.

Policy on publications of minutes

The policy of publishing the report of the Authority to the HPRA website, following the meeting in which it was approved, was reconfirmed.

14 Declaration of Interest and Ethics in Public Office Forms/Conflicts of Interest

The Authority was reminded that the Declaration of Interest forms and Public Office Forms were due to be submitted.

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

- Terms of Reference and Rules of Procedure Health Products Regulatory Authority
- Terms of Reference and Rules of Procedure of the HPRA Leadership Team

16 Finance Accounts – November 2022

The Authority noted the financial accounts for November 2022.

17 Licensing Activities – Tables of Licences Approved:

The Authority noted the tables specifying the authorisations approved by the Management Committee during the period 09/12/2022 to 13/01/2023.