

## Report of the Authority

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- Wednesday 8 May 2024 at 2pm (hybrid meeting)

Chair	Present	In attendance	Apologies
Mr M. Donnelly	Prof S. O’Kane	Dr L. Nolan, Chief Executive	-
	Dr J. Collins	Ms R. Purcell, Deputy Chief Executive	
	Dr D. Quinlan*	Mr S, d’Art, Director of ICT and Business Services*	
	Dr F. Kiernan	Dr J.G Beechinor, Director of Veterinary Sciences*	
	Mr B. Jones*	Corporate Affairs Manager	
	Prof R. Reilly	Corporate Affairs Administrator	
	Mr D. Holohan	Board Effect attendee* **	
	Dr P. Kilbane		

- Minutes taken by Ms K. Murphy, Secretary to the Committee
- \* Attended for part of the 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 their annual declarations.

### 3 REPORT OF THE MEETING OF 27 MARCH 2024

The report of the meeting of 27 March 2024 was approved.

### 4 HEALTH AND SAFETY

There was nothing to report.

### 5 CHIEF EXECUTIVE’S UPDATE

Specific points discussed included:

## **5.1 HPRC proposal on the regulation of dermal fillers**

27 Marc 2024

The Authority was informed that in December 2023, the HPRC submitted a paper on enhancing controls on the use of dermal fillers in Ireland to the Department of Health. The paper made a number of policy recommendations to enhance regulation of the use of dermal fillers. The Department and the HPRC continue to engage regarding the implementation of the recommendations which require a multi-agency approach.

## **5.2 High impact shortages – Medicines to treat ADHD**

An update on the ongoing global supply disruption to medicines for the treatment of attention deficit hyperactivity disorder (ADHD) was provided. This includes medicines containing guanfacine, atomoxetine, lisdexamfetamine dimesylate, and methylphenidate. The issue was escalated to the Medicines Criticality Group (MCAG) and engagement undertaken with relevant manufacturers. As a result of this proactive approach, notwithstanding some disruption in supply of individual medicines and strengths, there are at present sufficient stock levels for the Irish market. Close monitoring of national stock levels as well as engagement with the Department remain ongoing.

## **5.3 Medical Devices – Implementation of MDR and IVDR**

In response to ongoing issues regarding the implementation of the MDR and IVDR, the EU is proposing to conduct a targeted evaluation to gauge the functionality of the system. The HPRC is committed to the evaluation and using this opportunity to reinforce the importance of the regulations and need to address the challenges with implementation, and working with agencies within the network and EU Commission to achieve this.

## **6 AUTHORITY AWAY DAY**

The key discussion points from the Authority Away Day in January 2024 were summarised. The highlights from the day include innovation support, communication and engagement, and succession planning. The proposed next steps for each of these areas were agreed with members and updates will be added to future agendas to inform the Authority of key milestones.

## **7 FINANCIAL STATEMENTS FOR THE YEAR ENDED 31 DECEMBER 2023**

\*Ms R. Purcell joined the meeting

The Deputy Chief Executive presented the draft financial statements for the year ended 31 December 2023. The Authority was advised of, and agreed with, a proposal to charge depreciation on the premises cost. The Authority was informed that the recent C&AG audit has yet to be completed. It was noted that the Audit and Risk Committee (ARC) had reviewed the financial statements in detail and recommended them to the Authority. The Authority adopted the following, subject to there being no material audit adjustments:

- Draft Final Statements for the Year Ended 31 December 2023
- Reconciliation statement between draft financial statements and December 2023 management accounts
- Statement from the Authority Chair on the Code of Practice for the Governance of State Bodies for the year ended 31 December 2023

\*Ms R. Purcell left the meeting

## **8 WEBSITE DEVELOPMENT PROJECT**

\*Mr S. d'Art joined the meeting

An update on the current status of the website development project was given. Progress across all workstreams has either been completed or remains on target. The project focus has now shifted to managing development and testing phases. External testing is scheduled to commence later in the year and consideration will be given to involving stakeholders from external organisations with appropriate expertise to conduct an accessibility review. Following agreement of the design and visuals of the new website by the HPRA Leadership Team, some sample webpages were demonstrated to the Authority. The primary goals of the project, the simplification of information and the improvement of stakeholder accessibility, were emphasised. The go-live date for the new website remains Q4 2024.

\* Mr S. d'Art left the meeting

## **9 VETERINARY OVERVIEW**

\*Dr J.G Beechinor joined the meeting

The Authority was informed of the review of the veterinary business strategy which was undertaken following changes to the activities of the department stemming from the implementation of Regulation 2019/6, as well as other external factors such as Brexit.

\*Mr B. Jones left the meeting

Areas of consideration include changing application trends, structural organisation, fees, digital transformation, and stakeholder engagement. The Authority agreed with the suggested next steps which include a review of department resources. An update on the next steps will be provided to the Authority later in the year.

\*Mr B. Jones rejoined the meeting. Dr J.G Beechinor and Dr D. Quinlan left the meeting.

## 10 COMMITTEE UPDATES

Statutory Committee	Last meeting date	Updates
Audit and Risk Committee (ARC)	8 May 2024	<p>A verbal update was provided by the ARC Chair following the meeting on 8 May at which the ARC reviewed:</p> <ul style="list-style-type: none"> <li>- the financial statements;</li> <li>- the reconciliation statement between draft financial statements and December 2023 management accounts; and</li> <li>- the statement from the Authority Chair on the Code of Practice for the Governance of State Bodies for the year ended 31st December 2023.</li> </ul>

All were recommended to the Authority.

The Authority was informed that the installation of solar panels as originally planned would no longer proceed owing to the unsuitability of the copper roof and the significant expensive structural work that continuing with the project would incur. It was noted that there was a small area of the roof that could be used for a reduced number of panels and that this would go ahead subject to confirmation of suitability by the expert consultants.

The signed minutes from the 29 November 2023 ARC meeting were provided to the Authority.

Advisory Committee Veterinary Medicines (ACVM)	None since the last meeting	N/A
Advisory Committee Medical Devices (ACMD)	None since the last meeting	N/A
Advisory Committee Human Medicines (ACHM)	24 April 2024	An update from the ACHM meeting on the 24 April 2024 will be provided at the next Authority meeting.

## 11 AOB

There was nothing to report.

## **12 BOI CORPORATE MANDATE**

An updated mandate for Bank of Ireland was provided for information and signed by the Chair of the ARC as well as the Authority Chair.

## **13 HPRA UPDATES – CHANGES TO LEGISLATION COMPETENCIES, CODE OF CONDUCT ETC.**

### **13.1 Updates to terms of reference**

The Authority approved the proposed minor changes to the terms of reference (ToR) for the ACHM. Previous minutes of the 29 November 2023 erroneously listed the ToRs from the ACHM as having been approved by the Authority instead of the ACMD ToRs.

### **13.2 Changes to legislation**

- Commission Implementing Regulation (EU) 2024/875 of 21 March 2024
- Commission Implementing Regulation (EU) 2024/878 of 21 March 2024
- Commission Implementing Regulation (EU) 2024/916 of 26 March 2024
- Medicinal Products (Prescription and Control of Supply) (Amendment) (No.3) Regulations 2024 (SI 162/2024)

## **14 FINANCE ACCOUNTS – FEBRURY 2024 AND MARCH 2024**

The Authority noted the management accounts for February and March 2024.

## **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 15/03/2024 to 19/04/2024.

## **16 BOARD EFFECT**

\*Board Effect attendee joined the meeting

A member of Board Effect joined the meeting to deliver training to the Authority.

\*Board Effect attendee left the meeting

## **17 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.