

Thursday, 29 September 2022, 10:00 pm (HPRA Board Room)
Report of the Authority

Chair	Mr M. Donnelly
Present	Prof R. Reilly, Dr P. Kilbane, Prof S. O’Kane, Dr J. Collins, Mr D. Holohan, Mr B. Jones, Dr D. Quinlan, Dr. F. Kiernan
In attendance	Dr L. Nolan, Chief Executive (CE), Ms. R. Purcell, Deputy Chief Executive*
Apologies	
Minutes	Ms A. McGowan, Secretary to the Committees Ms K. Murphy, Secretary to the Committees

*attended for part of meeting

1 Welcome & Introductions

The Authority and the Chief Executive welcomed the newly appointed Authority member, Dr Fiona Kiernan, to her first meeting. Dr Kiernan was invited to give a brief overview of her career to date and areas of interest.

2 Declarations of interest / conflicts of interest

Prof S. O’Kane, Dr J. Collins and Dr P. Kilbane noted their conflicts as per the annual declarations received.

3 Report of the meeting June 2022

The report of the meeting of 23rd June 2022 was adopted.

4 Health and Safety

There was nothing to report.

5 Chief Executive’s Update

Specific points discussed included:

Open Call for Scientific Experts

An update was provided on the recruitment of scientific experts by the HPRA. It was noted that the recruitment had not been limited to only experts within Ireland. All experts would be required to submit declarations of interest (DoIs) in line with HPRA policy.

Staff Engagement

An overview was provided on ongoing staff engagement following the recent staff engagement survey. It was noted that a targeted survey was planned to be

circulated in November to HPRA staff. The Authority members were also informed that staff engagement is a key focus for both the HPRA Management Committee and departmental leadership teams.

Fee Review

The Authority were informed that the annual fee review was on-going and would be subject to a public consultation in October. 2023 will see increased payroll and energy and other costs reflecting centralised pay bargaining and ongoing inflation. It is estimated that the general fee increase for 2023 will be of the order of 9% to reflect these factors.

International Events hosted by the HPRA

- o Pharmaceutical Inspection Co-operation Scheme (PIC/S) Training Seminar and 50th Anniversary

The upcoming Pharmaceutical Inspection Co-operation Scheme week-long event which the HPRA is hosting in the first week in October 2022 was highlighted. The event includes the PIC/S Committee meeting, 50th Anniversary Symposium and PIC/S Seminar on "Inspecting the Pharmaceutical Quality System (PQS). It has attracted high attendance and interest from the international inspectorates.

- o ICMRA Summit

The HPRA will host the International Coalition of Medicines Regulatory Authorities (ICMRA) Summit over two days in November 2022. The Summit will consider key topics of relevance to the future of medicines regulation. The event will be attended by the leadership of international medicines agencies, and all the major global regulatory agencies will be represented.

Clinical Trials

A general update was given on the implementation of the new Clinical Trial Regulation and associated developments.

Communication Campaign

The Authority noted the successful reach of the recent digital media communications campaign. It was highlighted that the current communication campaign represented a concentrated effort to provide more education and promotion materials to younger populations.

Website Re-Development Project

The progress made since the last Authority meeting was noted. The Authority welcomed the comprehensive update on the project scheduled for the January 2023 meeting.

6 Overview of Planning Sodium Valproate Inquiry

**The Deputy Chief Executive joined the meeting*

An update was provided on the on-going preparatory work for the sodium valproate inquiry.

7 Risk Management: Periodic Risk Register Review

The Audit and Risk Committee (ARC) reviewed the Risk Register and recommended the register for review by the Authority.

An overview of the current risk register and updates was presented.

Discussion points included

- The challenging external recruitment market: The potential impact of this for the organisation is being closely monitored.
- The health and safety risk assessments for remote working required under health and safety legislation: An external contractor is being engaged to facilitate the conduct of these assessments.

The Authority approved the risk register.

**The Deputy Chief Executive left the meeting*

8 Service Planning

H1 2022 Report

An overview of the outturn of the 2022 service plan was presented. It was noted that the organisation had reached a higher number of achieved actions compared to the same time last year.

2023 high level planning

An update was provided on the ongoing service planning for 2023. The full-service plan for 2023 will be presented at the December Authority meeting.

In relation to capacity building initiatives being undertaken within the European regulatory networks, an overview of on-going developments was provided. As a member of the European regulatory network, the HPRA can be involved in relevant opportunities.

The Authority noted the recruitment of the Operations Excellence Manager.

The Authority commended the high level of outturn which had been achieved in the first half of 2022.

9 National Concert Hall Annual Support

The Authority considered and approved support for the National Concert Hall Health and Wellbeing programme.

10 Committee Updates

Statutory Committee	Last Meeting Date	<u>Update</u>
Advisory Committee Veterinary Medicines (ACVM)	14 September 2022	The ACVM Chair provided an update on the recent meeting of the ACVM.
Audit and Risk Committee (ARC)	28 September 2022	<p>The ARC Chair provided an update on the recent meeting of the ARC including an update on the risk register which was noted under item 7. Dr S. O’Kane was welcomed by the Chair as a new ARC member.</p> <p>The ARC reviewed and recommended the audit plan for reserves and the Investment Strategy document. It was noted that the ARC Terms of Reference had been reviewed and agreed without any amendments.</p>

11 AOB

There was nothing to report.

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

- In Vitro Diagnostic Medical Devices (Registration) Regulations 2022 (SI 365/2022) Medicinal Products (Prescription and Control of Supply) (Amendment) (No 4) Regulations 2022 (SI 402/2022)
- Medicinal Products (Control of Manufacture) (Amendment) (No 2) Regulations 2022 (SI 414/2022)
- Medicinal Products (Control of Wholesale Distribution) (Amendment) Regulations 2022 (SI 415/2022)
- Medicinal Products (Control of Placing on the Market) (Amendment) Regulations 2022 (SI 416/2022)
- European Communities (Clinical Trials on Medicinal Products for Human Use) (Amendment) Regulations 2022 (SI 417/2022)
- European Union (Clinical Trials on Medicinal Products for Human Use) (Principal) (Amendment) Regulations 2022 (SI 418/2022)

13 Financial Accounts May - July 2022

The Authority noted the financial accounts for May, June and July 2022.

14 Licensing Activities – Tables of Licences Approved

The Authority noted the tables specifying the authorisations approved by the Management Committee during the period 17/06/2022 to 16/09/2022.