HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

Wednesday, 07 December 2022, 1.30pm (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*, [redacted], Quality Manager*, [redacted], Káno Communications*, [redacted], RPS Group*
Apologies	-
Minutes	Ms K. Murphy, Secretary to the Committees

*attended for part of meeting

1 Welcome & Introductions
The Chair welcomed the members to the last Authority meeting of 2022.

2 Declarations of interest / conflicts of interest
Prof S. O'Kane and Dr P. Kilbane noted their conflicts as per the annual declarations received. Dr J. Collins noted that his conflict as President of Veterinary Ireland, as per his annual declaration, no longer applies.

3 Report of the meeting September 2022
The report of the meeting of 29th September 2022 was adopted.

4 Health and Safety
There was nothing to report.

5 Chief Executive's Update
Specific points discussed included:

Statistics on the Use of Animals in Scientific Procedures in Ireland in 2021
The positive trend in the declining use of animals in scientific procedures continued in 2021.

Veterinary Medicinal Product, Medicated Feed and Fertilizer Regulations Bill, 2022
The delay in the progression of the Veterinary Medicinal Product, Medicated Feed and Fertilizer Regulations Bill, 2022 was discussed. In line with this the implementation of the national requirement for a prescription for anti-parasitic veterinary medicines for food-producing animals, remains deferred.

Sodium Valproate
An update on the Sodium Valproate enquiry was provided and it was noted that the terms of reference (ToR) are expected before the end of the year.

Website Development Project
An update on the HPRA website development project was provided. The request for tender for an external web designer has been published and remains open. An audit of the documentation on the current website has been completed and an analysis of the workflow both into and within the website are ongoing.

People Strategy
It was noted that attendance at the workshops for the HPRAs first people strategy was well supported. The key pillars of the strategy were highlighted and the Authority were informed that a further staff engagement survey is planned.

Keep Well Mark Reaccreditation
The Authority were informed that the HPRA received reaccreditation of the IBEC KeepWell Mark.

Fee Consultation
It was noted that the HPRAs annual fees are proposed to increase generally by 9% and was subject to a public consultation. The results of that consultation have been published on the website.

Legalisation of cannabis
The Authority queried the status of legislation in relation to cannabis in Ireland. It was noted that the safety and efficacy position in relation to medicinal cannabis has not evolved further since this was last discussed.

6 Update HPRA Communication Strategy

* [redacted] joined the meeting

[redacted] were welcomed and introduced to the Authority members. An update was provided on the external audit, conducted over a number of months, by RPS to support the new HPRA Communication Strategy. As part of the audit external and internal coverage of the HPRA was reviewed and both internal and external stakeholders were interviewed including selected members of the Authority and the leadership team.

Findings arising from the audit showed the HPRA is considered a vital part of the national health system. The HPRA was seen to have a strong and relevant, issue focused media presence. The HPRAs proactive approach to engagement with stakeholders was deemed to be good with past communication campaigns, such

as Take 3 Minutes, being highlighted. Overall, the HPRA was considered to be a structured and serious organisation and the Chief Executive was commended for her considerable contribution to this.

The need to build further awareness amongst healthcare professionals, in particular general practitioners, as well as professional representative bodies, was discussed. It was noted that part of the website redesign, in particular the section dedicated to listing medications, may help address this. Whilst the HPRAs identification of audiences on social media platforms was lauded, increased prioritisation of specialist audiences such as health care professionals, as well as state departments, political organisations and government sectors was recommended. In line with this, increased focus should be directed to specialist media journals as well as regional newspapers.

In addition, the audit identified a resourcing imbalance within the communications section. To assist in addressing this imbalance a more integrated, organisation wide approach to communications was proposed. Additionally, increased communication resources were recommended. These recommendations will be further reviewed with additional resources expected in 2023 and 2024.

* [redacted] left the meeting

7 a) IBTS Annual Report

An overview of the background and history of the Irish Blood Transfusion Service (IBTS) annual report and findings during 2021 was provided. The IBTS operation was considered to comply with European and national requirements for collection, processing, and traceability. The report was adopted by the Authority.

b) Update on NHO Engagement

A discussion was had in relation to the arrangements between the National Haemovigilance Office (NHO) of the IBTS and the HPRA in relation to hemovigilance activities and engagements between both organisations over 2022.

8 Service Planning 2023

* [redacted] joined the meeting

The Authority were presented with the draft HPRA Service Plan 2023. It was noted that the service plan is structured to align with the Strategic Plan 2021-2025 with particular emphasis on strategic goal 5: Great people, great processes. Several actions have been carried across from 2022 including a review of pharmacovigilance, the sodium valproate enquiry, and the delay in uptake of applications under the Clinical Trial Regulation (CTR). The six key priorities under the plan were outlined and include collaboration with the Department of Health (DoH) in relation to sodium valproate, the review of regulation controls for codeine

containing over the counter products, continued engagement with stakeholders in relation to new regulations, the ongoing development of a new people strategy, the implementation of a digital transfer strategy, and the redevelopment of the website. A request was made by the Authority for an estimate of resources required to achieve these priorities. It was agreed this would be provided.

A mid-term review will be conducted in 2023 to review the individual actions under each goal to determine if any adjustments are required. Members of the Authority were invited to contribute to this review. A proposal to reduce the current HPRA strategic plan from a five year to a three-year period was endorsed.

* [redacted] left the meeting

9 Budget 2023

* Ms R Purcell joined the meeting

The Deputy Chief Executive presented the budgets for 2023, which were recommended to the Authority by the Audit and Risk Committee. The detailed budgets of the HPRA were reviewed and following a discussion were approved by the Authority.

* Ms R Purcell left the meeting

10 Follow Up from September Thematic Discussion – Next Steps

The next steps as outlined in the accompanying paper were agreed. A presentation on the HPRA's innovation office will be presented to the Authority at the January meeting.

11 Committee Updates

Statutory Committee	Last Meeting Date	Updates
Audit and Risk Committee (ARC)	1 December 2022	An overview was provided of the 1 December meeting. Highlights from the meeting included the recommendation of the 2023 budget.
Advisory Committee for Human Medicines (ACHM)	None since last meeting	The report was taken as read.
Advisory Committee for Medical Devices (ACMD)	21 November 2022	The report was taken as read. The requirement for new members was raised.

Advisory Committee for Veterinary Medicines (ACVM)	None since last meeting	Nothing to report.

12 AOB

There was nothing to report.

13 Internal Authority Evaluation 2022

The Authority were informed that the annual Authority internal evaluation, as required by the Code of Practice for the Governance of State Bodies, would be circulated after the meeting for completion.

14 Authority Meeting Dates 2023

The proposed 2023 Authority meeting dates were reviewed, amended, and agreed.

15 Finance Accounts August –October 2022

The Authority noted the financial accounts for August, September, and October 2022.

16 Licensing Activities – Tables of Licences Approved

The Authority noted the tables specifying the authorisations approved by the Management Committee during the period 23/09/2022 to 02/12/2022.

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.