HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

Wednesday, 11 May 2022, 2:00 pm (hybrid meeting)
Report of the Authority

Chair	Mr M. Donnelly
Present	Prof E. Keane, Dr P. Kilbane, Prof S. O'Kane, Prof R. Reilly**, Dr J. Collins, Mr D. Holohan, Mr B. Jones
In attendance	Dr L. Nolan, Chief Executive (CE), Ms. R. Purcell*, Deputy Chief Executive, Dr. N. MacAleenan*, Director of Medical Devices
Apologies	Dr D. Quinlan
Minutes	Ms. A, McGowan, Corporate Affairs Manager (Acting)

*attended for part of meeting
**attended the meeting remotely

1 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 and abstained from attending related parts of the meeting, as appropriate.

2 Authority Report

The report of the meeting of 23 March 2022 was adopted.

3 Health and Safety Update

There was nothing to report.

4 Medical Devices

4.1 Discussion on strategic issues

The key pillars of the EU medical device regulatory system were outlined to the Authority. The HPRA's role was clarified as primarily being market surveillance, and overseeing the notified body in Ireland rather than performance of CE marking for medical devices.

The HPRA outlined the key challenges facing the regulatory system at present, which included notified body capacity, coordination on safety monitoring, governance and harmonised application. Notified body capacity is recognised as the largest of the challenges facing the sector.

The Authority proposed and discussed potential solutions. The importance of addressing the issues at a systemic level was emphasised and the Authority agreed a strong national position was important. It was noted that the HPRA medical devices section might require more resources once a national position is established.

The Authority highlighted the importance of maintaining focus on potential patient impacts.

4.2 Advisory Committee Medical Device (ACMD) – Update from 04 May strategic decision

An overview of the meeting of the ACMD focusing on the strategic issues affecting the regulatory network was provided. The Chairman of the Authority attended the meeting as an observer. The discussion focused on patient safety and the quality of devices on the market. The ACMD emphasised the need to focus on the national impact on patients and the healthcare system and to engage with other parts of Government to develop a cohesive national position.

5 Chief Executive update

Specific points discussed included:

Secretary General

The meeting with the Secretary General and HPRA was rescheduled and it now due to be held on 12 May 2022.

Low Dose Codeine Preparations

An update was provided on low dose codeine preparations and considerations on the availability of these medicines as OTC products.

Sodium Valproate

The DOH have indicated that the Terms of Reference for the sodium valproate enquiry will be finalised shortly

Update on Arthropharm Ltd Appeal

An update was provided on the outcome of the legal case in the Court of Appeal by Arthropharm (Europe) Limited Pharmaceuticals in relation to the approval of a generic product, Osteopen 100mg/ml solution. The Court of Appeal rejected the appeal and awarded costs to the HPRA and the manufacturer of the generic product, Chanelle Pharmaceuticals Manufacturing Ltd. The company has 21 days to appeal this decision.

Update on antiparasitic veterinary medicines for food-producing animals

The implementation of legislation related to the change of antiparasitic veterinary medicinal products for food-producing animals to prescription control has been delayed until June 01 2022.

Hormone Replacement Therapy Products

There are current challenges regarding the intermittent supply of hormone replacement therapies (HRT), notably transdermal patches due to significant

increases in demand for HRT medicines. The HPRA shortages team is monitoring the situation and is investigating whether available regulatory interventions can help alleviate supply issues. The Minister for Health has written to industry to requesting consideration of possible solutions including identifying products on alternative markets.

Recruitment
A query was raised on ongoing recruitment processes since the return to office. It was noted that recruitment is going well in general. Some delays are being observed in recruitment to administrative based roles.

6 Audit and Risk Committee (ARC)

An update was provided by the Chair of the Audit and Risk Committee. Specific points discussed included:

Reconciliation between December management accounts and financial statements
A reconciliation between the financial results contained in the December management accounts and the draft financial statements for the year ended 31 December 2021 was noted.

The statement from the Chair of the Authority to the Minister on the Code of Governance for State Bodies was reviewed and agreed by the ARC. The Chair signed the statement during the Authority meeting.

7 2021 Financial Statements for approval and adoption

The Deputy Chief Executive presented the draft financial statements for the year ended 31 December 2021. The financial statements, were approved and adopted.

System of Internal Controls Statement
The System of Internal Controls statement 2021 was reviewed by the ARC and recommended for presentation to the Authority. Under a written procedure held in advance of the meeting, the Authority approved and agreed that the controls in place were considered appropriate.

8 Financial Training

Authority members were provided with high level training on financial statements. Further in-depth training may be organised at a later date.

9 AOB

There was nothing to report.

10 Administrative Matters

10.1 Approach for June Authority Meeting

It was noted that the June Authority meeting which is usually focused on thematic discussion may need to be rescheduled to September. Authority members were asked to identify potential topics for discussion.

10.2 Authority Vacancies:

An update was provided on the status of the ongoing recruitment process for the upcoming vacancy on the Authority.

11 COVID-19 update

An update was provided in relation to the national booster vaccination campaign. An overview of the additional COVID-19 therapeutics and the ongoing status of their evaluations was provided.

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

- Misuse of Drugs Act 1977 (Controlled Drugs) (Declaration) Order 2022 (SI 176/2022)
- European Union (Protection of Animals used for Scientific Purposes) (Amendment) Regulations 2022 (SI 205/2022)

13 Management Accounts Feb and Mar 2022

The Authority noted the management accounts for February and March 2022.

14 Licensing activities

The Authority noted the tables specifying the authorisations approved by the Management Committee during the period 18/03/2021 to 29/04/2022.