

Minutes of HPR Leadership Team (HLT) – Licensing and Regulation Section

Friday 13 October 2023 at 9.30am

Hybrid Teams call and CEO’s Meeting Room 3rd Floor

Chair	Dr L. Nolan, Chief Executive
Present	Ms E. Stuart, Director of Human Resources and Change Dr N. MacAleenan, Director of Medical Devices Dr J.G. Beechinor, Director of Veterinary Science Ms G. Power, Director of Compliance Ms S. Curran, Director of Human Products Monitoring Ms R. Purcell, Deputy Chief Executive
Apologies:	Dr F. Lonsdale, Director of Human Medicines Mr S. d’Art, Director of ICT and Business Services
Minutes:	Ms K. Murphy, Secretary to the Committees

(Please note that commercially sensitive information, personal data, and sensitive details in relation to pending prosecutions have been removed from these minutes).

*Approved via written procedure

**Attended part of the meeting

1 Adoption of the agenda

The meeting adopted the agenda.

2 Declaration of Interest

There was nothing to report.

3 Adoption of the minutes of the last meeting

The minutes of the meeting of 06 October 2023 were adopted and signed.

4 Matters Arising

Report relating to CHI

An update was provided on the ongoing situation in CHI.

5 Public Health Issues

There was nothing to report.

6 Product Issues

Ozempic

An issue relating to the falsification of Ozempic packs discovered in the UK was discussed. To date there is no evidence that the falsified batch has entered the Irish market. An investigation at European level is ongoing. It was agreed that the HPR will issue communication to wholesalers and give consideration to issuing wider communication.

Topiramate

It was noted that the CMDh has adopted the PRAC recommendation in relation to measures to avoid topiramate exposure in pregnancy. The HPRA continues to liaise with the relevant national stakeholders.

Valproate

A national Direct Healthcare Professional Communication (DHPC) has been issued regarding the EMA review of a study in children whose fathers were treated with valproate. A stakeholder meeting to discuss the issue is being organised by PRAC for November.

7 Rejections, Suspensions, Revocations

There was nothing to report.

8 Licensing Tables

The attached tables were approved.

9 Any Other Business

There was nothing to report.

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Signed _____

Date _____