

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

Friday 14 June 2024 at 9.30am

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

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

(Please note that certain information, such as personal data, confidential/commercially sensitive information, and pending prosecutions may 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

Dr G. Power declared a conflict of interest in relation to the tables 1.17 and 1.18 and therefore did not consider these in her written approval. Dr L. Nolan declared a conflict of interest in relation to tables 1.17 and 1.18 and left the meeting during the consideration of these tables. Ms R. Purcell assumed the role of Chair in Dr Nolan’s absence.

3 Adoption of the minutes of the last meeting

The minutes of the meeting of the 07 June 2024 were adopted and signed.

4 Matters Arising

There was nothing to report

5 Public Health Issues

PRAC highlights

An update was given on the highlights from the May PRAC meeting.

6 Product Issues

Topiramate pregnancy prevention programme as well as revised valproate educational materials

It was noted that educational materials for the topiramate pregnancy prevention programme as well as revised valproate educational materials for women and men were recently published on the HPRAs website

7 Rejections, Suspensions, Revocations

There was nothing to report.

8 Licensing Tables

The attached tables were approved.

9 Any Other Business

Article 51 referral case A5155358

The HLT decided that the device should be classified as Class III under rule 18, Annex VIII of Regulation (EU) 2017/745.

** Ms Elizabeth Stuart and Ms A. Holly left the meeting

AOB HLT items

A number of HLT matters were discussed which were not related to Licensing and Regulatory matters.