

Minutes of the HPRA Leadership Team

Licensing and regulation section

- Friday 29 August 2025 at 9.30am
- Hybrid Teams call and CEO's meeting room 3rd floor

Chair	Present	Apologies
Dr L. Nolan, Chief Executive	Mr S. d'Art, Director of ICT and Business Services	Dr F. Lonsdale, Director of Human Medicines*
	Ms G. Power, Director of Compliance	Ms R. Purcell, Deputy Chief Executive
	Ms E. Stuart, Director of Human Resources and Development	Ms S. Curran, Director of Human Products Monitoring
	Dr N. MacAleenan, Director of Medical Devices	
	Dr J.G. Beechinor, Director of Veterinary Science	

Minutes taken by Minutes taken by 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 DECLARATIONS OF INTEREST

There was nothing to report.

3 ADOPTION OF THE MINUTES OF THE LAST MEETING

The minutes of the meeting of 22 August 2025 were adopted and signed.

4 MATTERS ARISING

4.1 Pharmacovigilance non-compliance

The MAH involved in a recent inspection have confirmed that no product will be placed on the Irish market until full compliance with regulatory requirements has been met.

5 PUBLIC HEALTH ISSUES

There was nothing to report.

6 PRODUCT ISSUES

6.1 Trimethylbenzoyl Diphenylphosphine Oxide (TPO)

The upcoming prohibition order which will take effect on 1 September 2025, was noted. The HPRA will liaise with the HSA in relation to this.

7 REJECTIONS, SUSPENSIONS AND REVOCATIONS

There was nothing to report.

8 LICENSING TABLES

The relevant tables submitted were approved.

9 AOB

9.1 NSAI

An update was provided on the recent EU joint assessment for re-designation of NSAI under the MDR. Next steps remain under discussion.

9.2 Corporate risk management report

The corporate risk management report was discussed and agreed.