

Minutes of the HPRA Leadership Team

Licensing and regulation section

- Friday 25 July 2025 at 9.30am
- Hybrid Teams call and CEO's meeting room 3rd floor

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

Minutes taken by Ms A. Holly, Corporate Affairs Manager

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 18 July 2025 were adopted and signed.

4 MATTERS ARISING

There was nothing to report.

5 PUBLIC HEALTH ISSUES

5.1 NSAI

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

5.2 Pharmacovigilance non-compliance

A further update was provided on the approach to be taken following a recent inspection of a Marketing Authorisation Holder (MAH).

6 PRODUCT ISSUES

6.1 Committee for Medicinal Products for Human Use (CHMP)

An update was provided on the outcome of the CHMP vote on Kisunla.

7 REJECTIONS, SUSPENSIONS AND REVOCATIONS

There was nothing to report.

8 LICENSING TABLES

The relevant tables submitted were approved.

9 AOB

9.1 NVPS

An update was provided confirming that the implementation of S.I. No. 51 of 2025 has been deferred until 1 December 2025 to allow additional time for full adoption of the NVPS.