

Minutes of the HPRA Leadership Team Licensing and regulation section

- Friday 18 July 2025 at 09.30am
- Hybrid Teams call and CEO's meeting room 3rd floor

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

Minutes taken by Ms K. Murphy.

Please note that certain information, such as personal data, confidential/commercially sensitive information, and pending prosecutions may have been removed from these minutes.

1 ADOPTION OF THE AGENDA

The meeting adopted the agenda.

2 DECLARATIONS OF INTEREST

There was nothing to report.

MGT-F0035-3

^{*}Approved via written procedure

^{**}Attended part of the meeting

3 ADOPTION OF THE MINUTES OF THE LAST MEETING

The minutes of the meeting of 11 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

An update was given on a recent inspection of a MAH.

6 PRODUCT ISSUES

6.1 Committee for Medicinal Products for Human Use (CHMP)

An update was provided on an ongoing product discussion at CHMP.

6.2 Divence IBR Marker Live

An update of Committee for Veterinary Medicinal Products (CVMP) discussions on Divence IBR Marker Live was provided.

7 REJECTIONS, SUSPENSIONS AND REVOCATIONS

There was nothing to report.

8 LICENSING TABLES

The relevant tables submitted were approved.

9 AOB

9.1 Sodium Valproate

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The recent approval of the data protection SIs in relation to the Sodium Valproate inquiry by the Seanad and the Dáil was noted.

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