

## Minutes of the HPRA Leadership Team

### Licensing and regulation section

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- Friday 05 September 2025 at 9.30am
- Hybrid Teams call and CEO's meeting room 3<sup>rd</sup> floor

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

Minutes taken by 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

\*\*Dr Lorraine Nolan and Ms Grainne Power declared a conflict of interest and left the meeting for table 1.17 and 1.18. 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 29 August 2025 were adopted and signed.

### **4 MATTERS ARISING**

There was nothing to report.

### **5 PUBLIC HEALTH ISSUES**

#### PRAC Update

An update was given on the September PRAC meeting.

### **6 PRODUCT ISSUES**

There was nothing to report.

### **7 REJECTIONS, SUSPENSIONS AND REVOCATIONS**

There was nothing to report.

### **8 LICENSING TABLES**

The relevant tables submitted were approved.

### **9 AOB**

#### **9.1 Article 51 referral case A5155477**

##### Article 51 referral case A5155477

The HLT considered a referral under Article 51(2) of Regulation (EU) 2017/745 concerning the classification of wound dressings incorporating Bismuth Tribromophenate (BTP). The HLT endorsed the recommendation of the Medical Devices Department and determined that the devices shall be classified as Class IIb under Rule 4 of Annex VIII to the MDR.

##### Codeine Classification Review

An update was provided on the ongoing review of the classification of codeine-containing medicines.

Sodium Valproate

An update was provided on the ongoing sodium valproate inquiry.