

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

**Friday 31 May 2024 at 9.30am**

**Hybrid Teams call and CEO's Meeting Room 3<sup>rd</sup> Floor**

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

Apologies: /

Minutes: 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 and Dr L. Nolan declared a conflict of interest in relation to the tables 1.17 and 1.18 and left the meeting during the consideration of these tables. Ms E. Stuart 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 24 May 2024 were adopted and signed.

## 4 Matters Arising

There was nothing to report.

## 5 Public Health Issues

There was nothing to report.

## 6 Product Issues

### Hydroxyprogesterone caproate medicines

The recent PRAC recommendation to suspend the marketing authorisations for medicines containing Hydroxyprogesterone caproate was highlighted. It was noted that the product is not authorised in Ireland.

### Tecfidera and Fumaderm

Issues arising from a number of court cases relating to Tecfidera and Fumaderm were discussed.

**7 Rejections, Suspensions, Revocations**

Suspension of MA for Kexxtone

The recent CVMP suspension and recall of the marketing authorisation of Kexxtone was noted.

**8 Licensing Tables**

The attached tables were approved.

**9 Any Other Business**

NSAI

An update was given on the on-site assessment ahead of this occurring in the coming week.