Engaging in the EU Regulatory Network: Member State Journeys

Dr Lorraine Nolan

19th March 2021
Health Products Regulatory Authority of Ireland

Scope
Health Products Regulatory Authority of Ireland

Expertise in Agriculture and Biopharmaceuticals

- **9 OF THE TOP 10 global med tech companies**
- **7TH LARGEST EXPORTER** of medicinal and pharmaceutical products in the world in 2014
- **€39BN IN ANNUAL EXPORTS** of pharma, bio and chemistry produce
- **75 PHARMACEUTICAL COMPANIES** operate in Ireland
- **10 OF THE TOP 10 world’s pharmaceutical companies**
Health Products Regulatory Authority of Ireland

Targeted Approach to Greater Engagement Human Medicines

01
Key Strategic Objective
Greater engagement and commitment to European system identified as a central pillar to key strategic objectives

02
Targeted Recruitment and Expertise Development
Biostatistics, PK and clinical expertise in identified therapeutics areas to facilitate strategic goals

03
Scientific Advice and Committees
Specifically identified as way to gain confidence exposure, knowledge and increase internal capacity.
Health Products Regulatory Authority of Ireland

Human Medicines

<table>
<thead>
<tr>
<th>Category</th>
<th>2015</th>
<th>2019</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rapp Regular</td>
<td>1</td>
<td>11</td>
</tr>
<tr>
<td>Co-rapp</td>
<td>6</td>
<td>5</td>
</tr>
<tr>
<td>Rapp MNT</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>Co-rapp MNT</td>
<td>2</td>
<td>0</td>
</tr>
<tr>
<td>Assessor MNT</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td><strong>Scientific Advice</strong></td>
<td><strong>51</strong></td>
<td><strong>102</strong></td>
</tr>
</tbody>
</table>
European Engagement - 2019 Snapshot

- Lead Member State for the assessment of 13 of the MRPs and 38 of the DCPs
- Rapporteur or co-rapporteur in respect of 24 new veterinary medicines
- Leading NCA in the EU for ongoing work in 2019
Health Products Regulatory Authority of Ireland

Expanding Expertise and Skills - Adapting to Innovative Technologies

Software – Update infrastructure and capacity to capitalise on new technologies and digitalisation

Data Analytics - AI and Machine Learning

Innovative products - Cell and gene therapies (CGT’s); combination products