



Engaging in the EU Regulatory Network: Member State Journeys

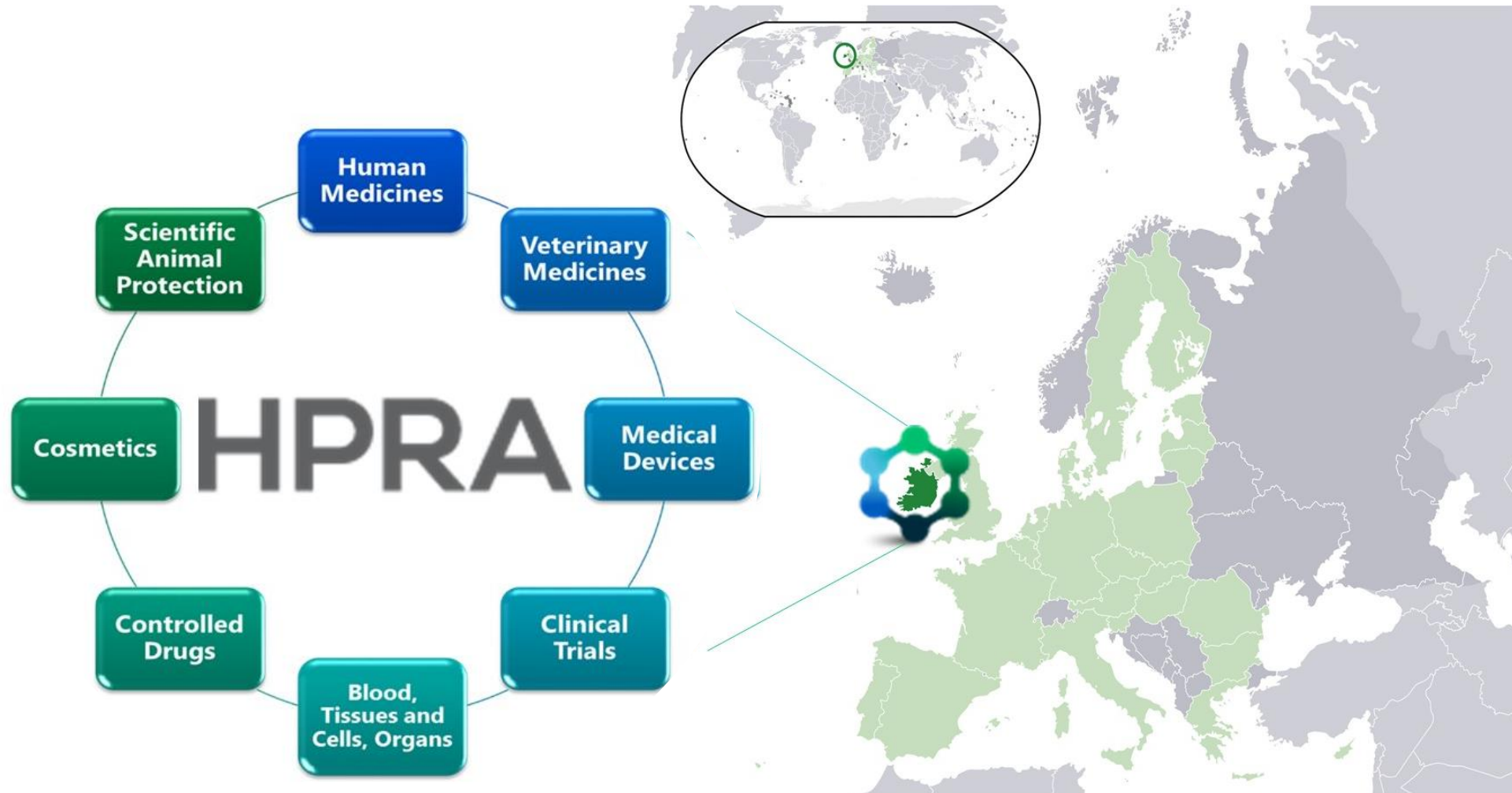
Dr Lorraine Nolan

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



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Targeted Approach to Greater Engagement Human Medicines



Health Products Regulatory Authority
Strategic Plan 2016 – 2020

01

Key Strategic Objective

Greater engagement and commitment to European system identified as a central pillar to key strategic objectives



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH



02

Targeted Recruitment and Expertise Development

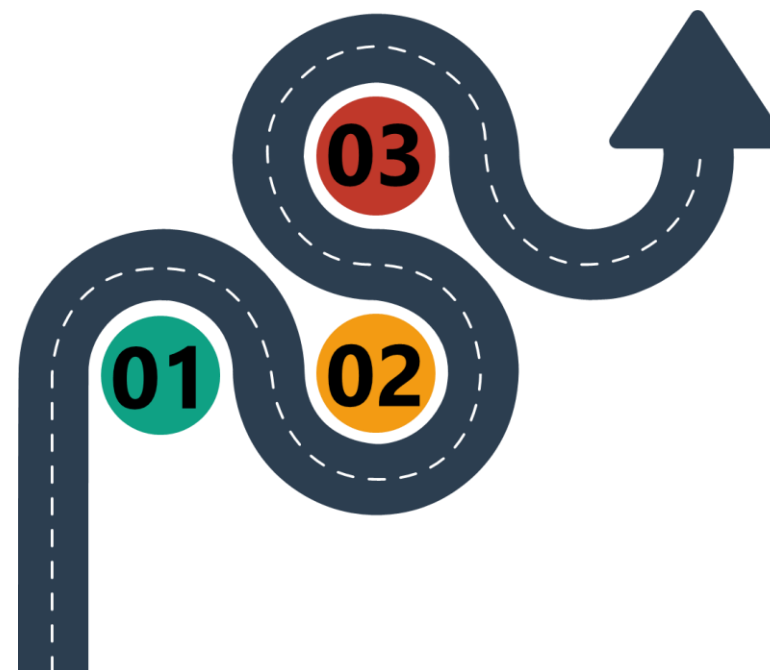
Biostatistics, PK and clinical expertise in identified therapeutics areas to facilitate strategic goals



03

Scientific Advice and Committees

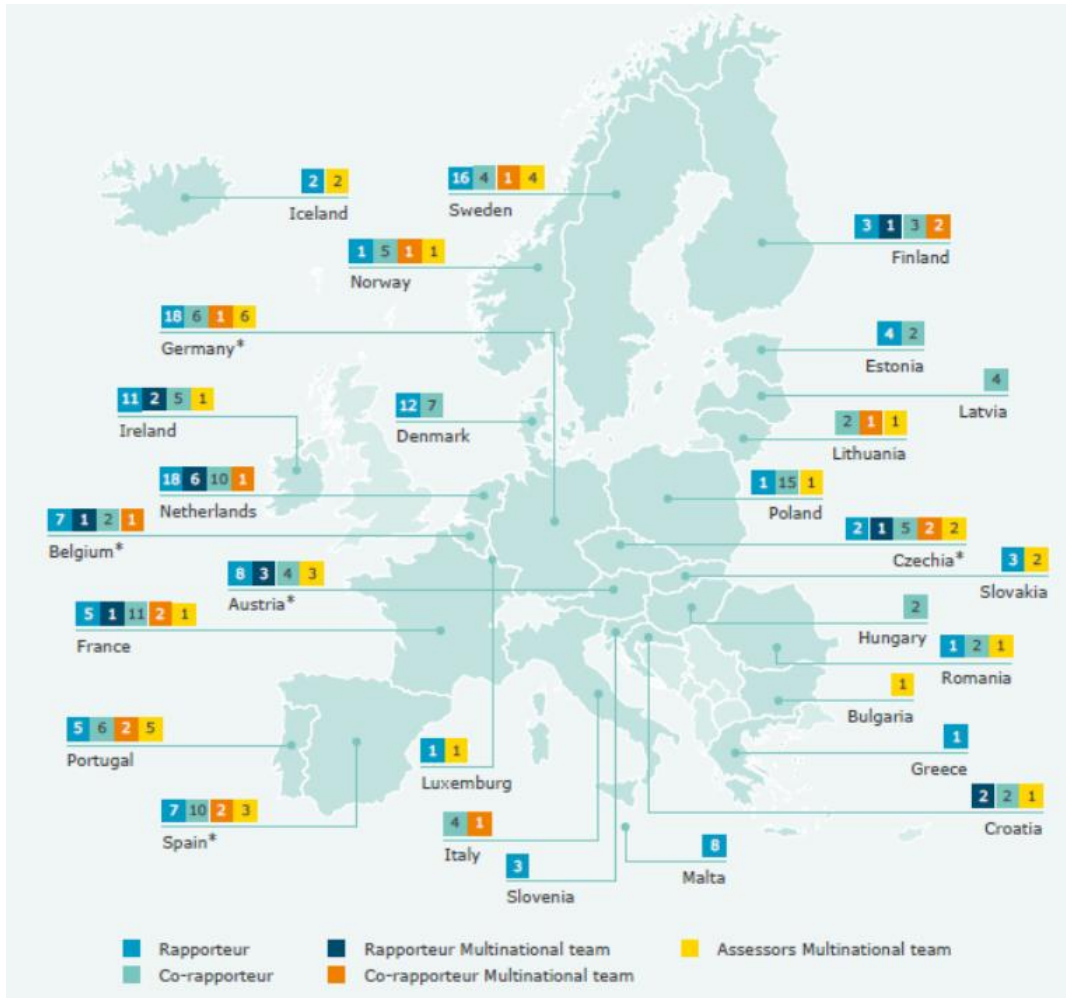
Specifically identified as way to gain confidence exposure, knowledge and increase internal capacity.





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Human Medicines



	2015	2019
Rapp Regular	1	11
Co-rapp	6	5
Rapp MNT	1	2
Co-rapp MNT	2	0
Assessor MNT	0	1
Scientific Advice	51	102



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Veterinary Medicines

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





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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