

Supporting Innovation through Regulation and Science

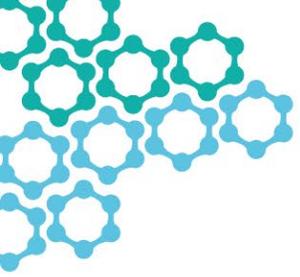
Larry O'Dwyer,

Scientific Affairs Manager, HPRA & Co-Chair EU-Innovation Network



EMA SME Stakeholder roundtable

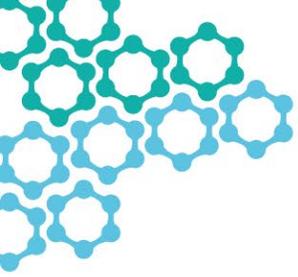
27th November 2020



Presentation Overview

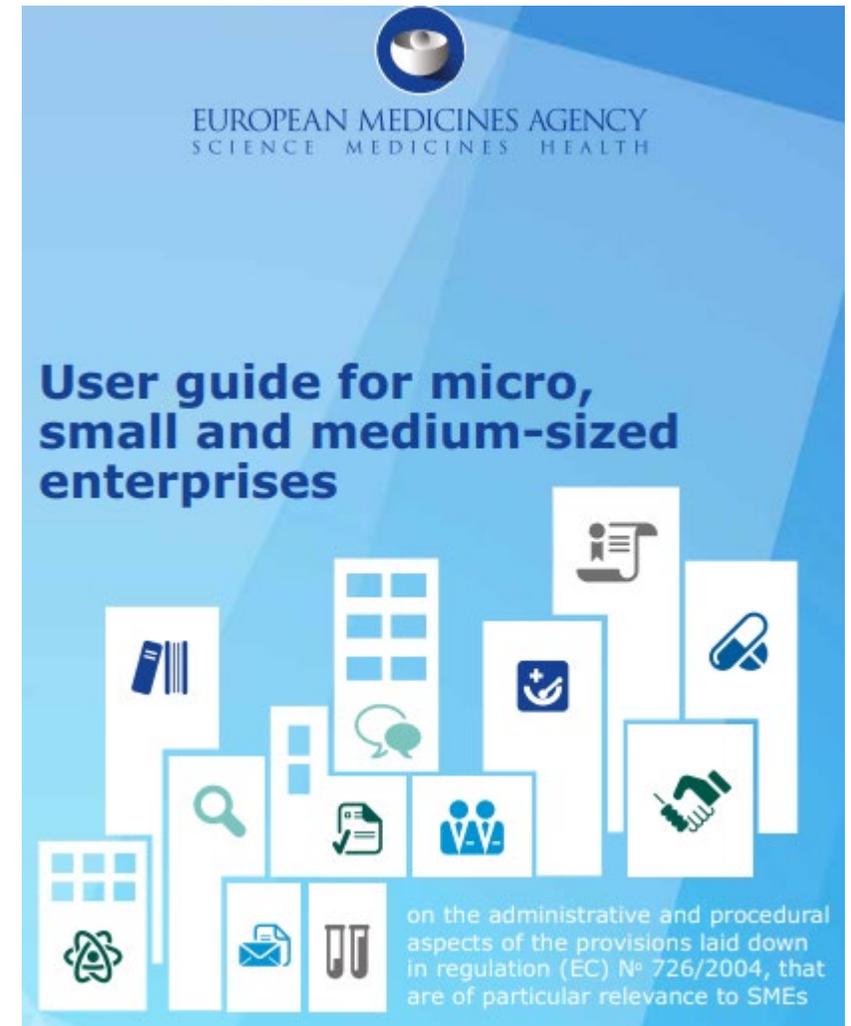
- Supports for Innovation at national level
- Role and Mandate of the EU-Innovation Network (EU-IN)
- Ongoing initiatives to deliver on the mandate of the EU-IN

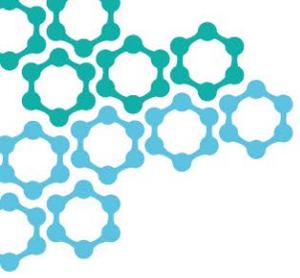




National Supports for SMEs

- Need to support translation of science into health products and technologies for the benefits of patients
- Facilitate early dialogue and access to knowledge and expertise
- Ensure that regulation facilitates safe and timely access
- Annex 1 of EMA User Guide includes an overview of national provisions for SMEs





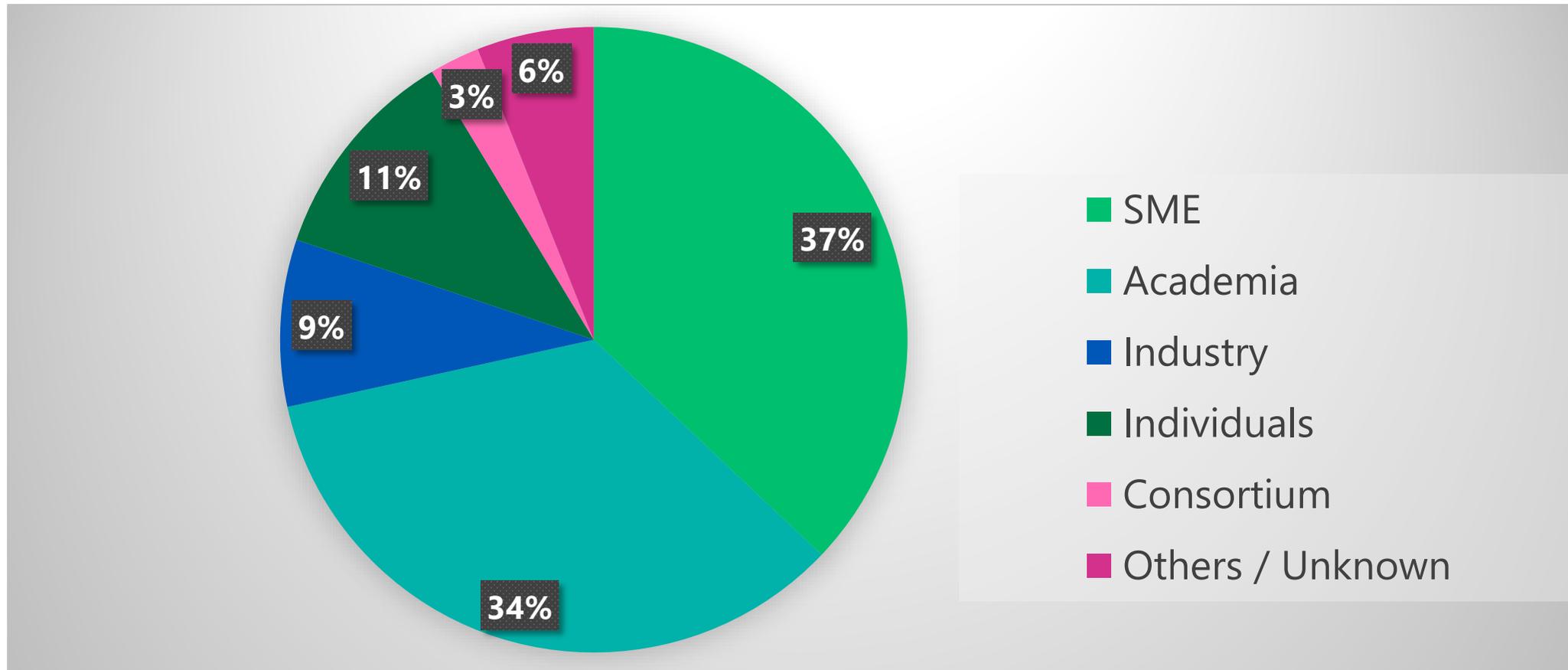
National Innovation Offices

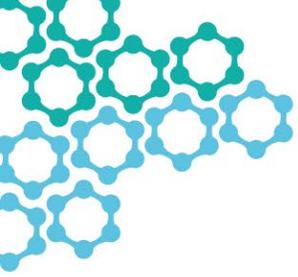
- An initial point of contact for innovators to submit queries in relation to innovative products and technologies within the NCA's remit
- Queries can be submitted at any stage of development including initial research
- Help to identify relevant guidance or regulatory considerations
- Identification of other regulatory supports at both national and European level that can be accessed as development proceeds, e.g. scientific advice





Origin of Queries to the HPRA's Innovation Office





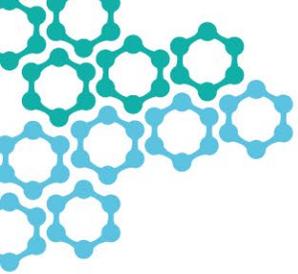
EU-Innovation Network

- Joint HMA and EMA mandate reflecting the European Medicines Regulatory Network Strategy
- National innovation offices and the EMA's Innovation Task Force
- Increase visibility and encourage use of the regulatory supports currently available at national and EU level
- Address gaps in early regulatory support to innovation

Innovators
meet
regulators



> Welcome to the EU
Innovation Network // EU-IN



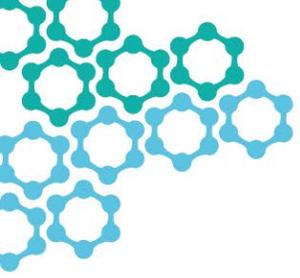
Mandate of the EU-IN and related initiatives

- Share experience and knowledge from NCAs and EMA
- Identify emerging trends that may require new regulatory approaches / additional expertise
 - Horizon Scanning
- Make the regulatory support available more visible and attractive to innovators from an early stage



STARS

STRENGTHENING
REGULATORY
SCIENCE



Mandate of the EU-IN and related initiatives

- Discuss and share opinions on borderline and classification issues (in collaboration with other groups)



- Act as an integrative element helping to solve the challenges faced in national scientific or regulatory advice
 - Simultaneous National Scientific Advice

Simultaneous National Scientific Advice

Discussions and Submission

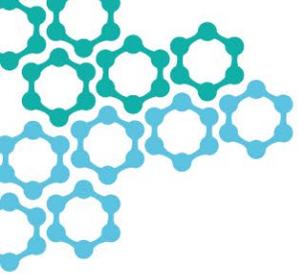
- Request
- Agreement on Timeline
- Submission to each NCA

NCA Review

- Independent initial review by each NCA
- Meeting / TC between the NCAs

Outcome to Applicant

- SNSA Meeting / TC
- Meeting minutes reflecting the opinions from both NCAs
- Questionnaire to applicant



To conclude

We are strengthening the EU regulatory network in order to:

- Share knowledge between the various Innovation Offices of NCAs and the EMA
- Ensure the EU regulatory network is prepared to regulate innovative products and disruptive technologies
- Flag regulatory challenges to be addressed
- Identify and address training needs
- Improve our capabilities to help innovators – academic groups, SMEs, larger companies – to bring innovations forward from national level to the EU level



3 July 2020
EMA/321483/2020

European medicines agencies network strategy to 2025
Protecting public health at a time of rapid change