

SME and Innovation Support in the European Medicines Regulatory Network

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EMA roundtable on 20th anniversary of the SME
Regulation

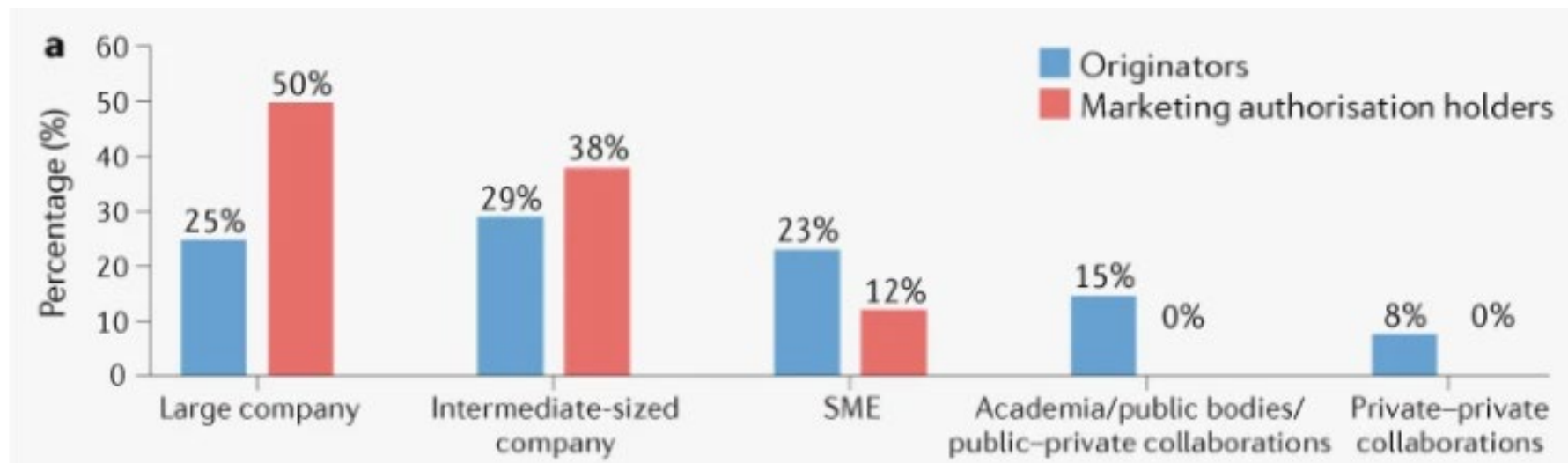


Overview

- Importance of SMEs as part of the innovation ecosystem
- EU-Innovation Network Activities
- Supports for innovation at national level

SME Contribution to Pharmaceutical Innovation

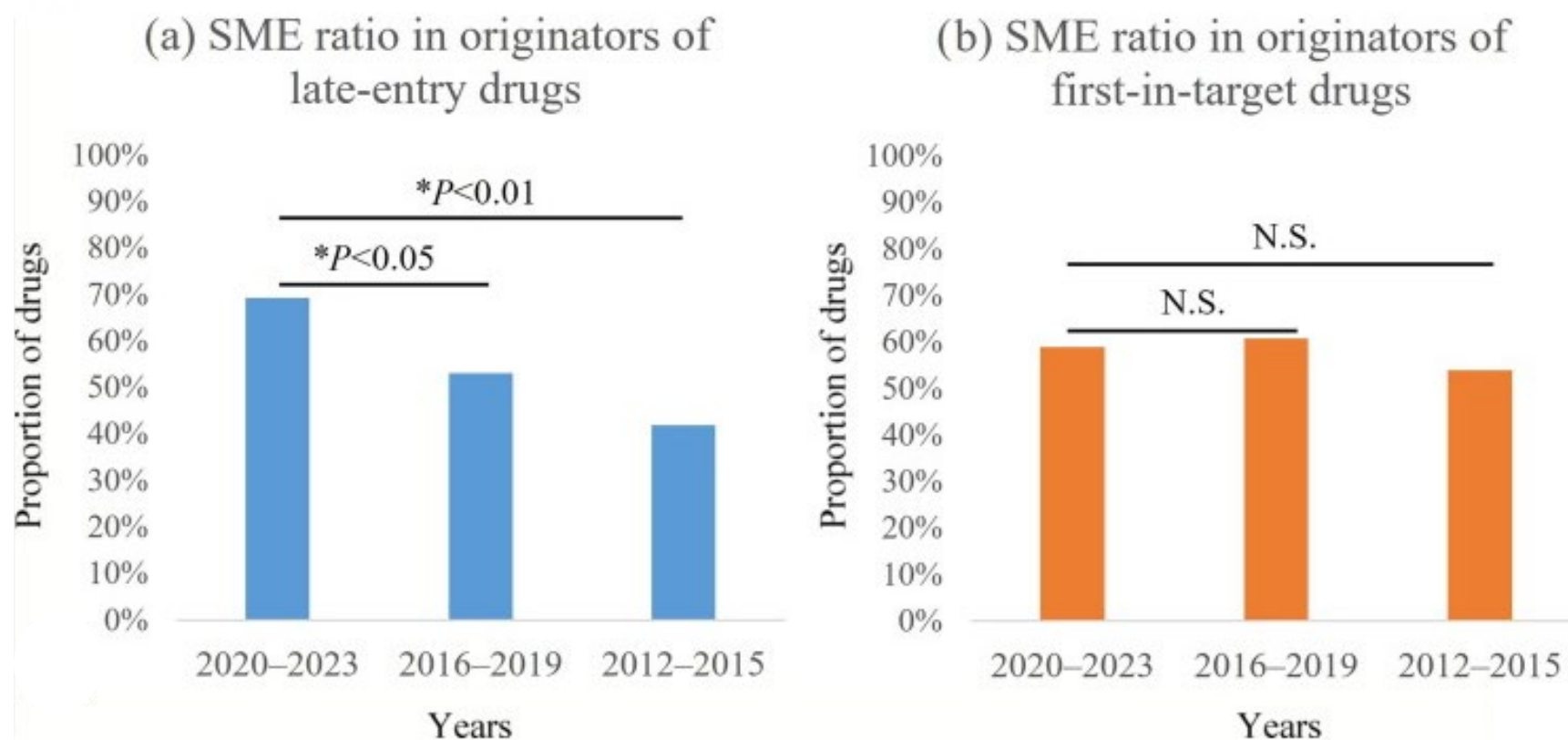
Originator and MAH for approved new and innovative medicines in the EU 2010-2019



Source: *Pharmaceutical Innovation Sourcing*, Provansal, Dooley and Ziogas, *Nature Reviews Drug Discovery* 21, 627 (2022)

SME Contribution to Pharmaceutical Innovation

Involvement of SMEs in new drugs approved by the US FDA



Source: Increased Contribution of small companies to late-entry drugs: a changing trend in FDA-approved drugs during the 2020s, Okuyama, Drug Discovery Today 29, 2 (Feb 2024)

Innovation Ecosystem



Credit: Monash University,
Australia

EU-Innovation Network (EU-IN)

- Joint HMA / EMA mandate
- National innovation offices and the EMA's innovation task force
- Increase visibility and encourage use of regulatory supports at national and EU level
- Address gaps in early regulatory support for innovation

Innovators
meet
regulators



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

Activities of EU-Innovation Network

Stakeholder engagement

- Dialogue with developers
- Promote and optimise regulatory supports

Horizon scanning:

- Trends in medicine R&D
- Reports and recommendations

Promote involvement in regulatory science projects

- Support EU Regulatory Science platform
- Guideline on CA involvement



Borderline products

- Discussions on regulatory status of novel products
- Collaboration with other regulatory frameworks

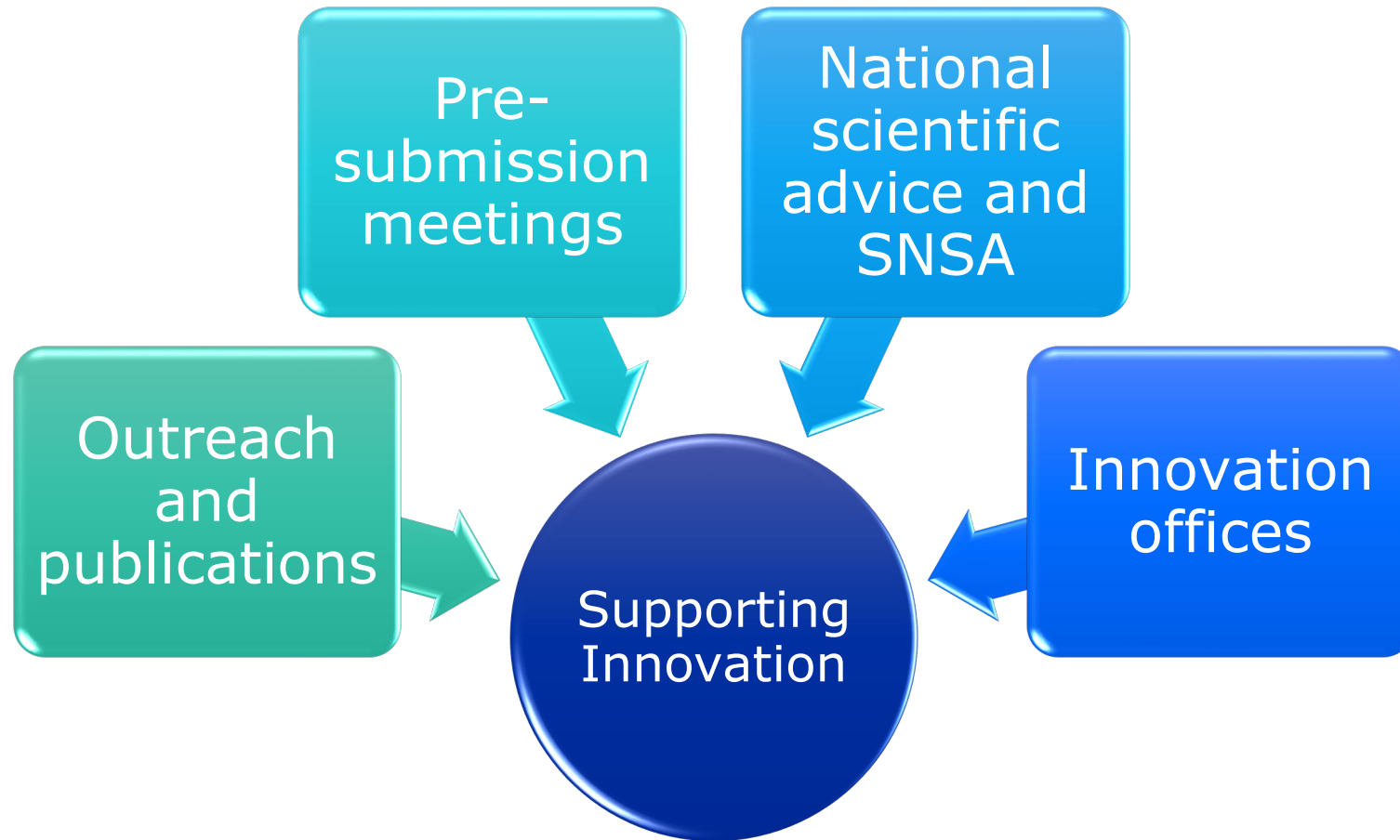
Promote collaboration across the EMRN

- ACT EU
- Network Data Steering group
- IncreaseNET

Simultaneous National Scientific Advice

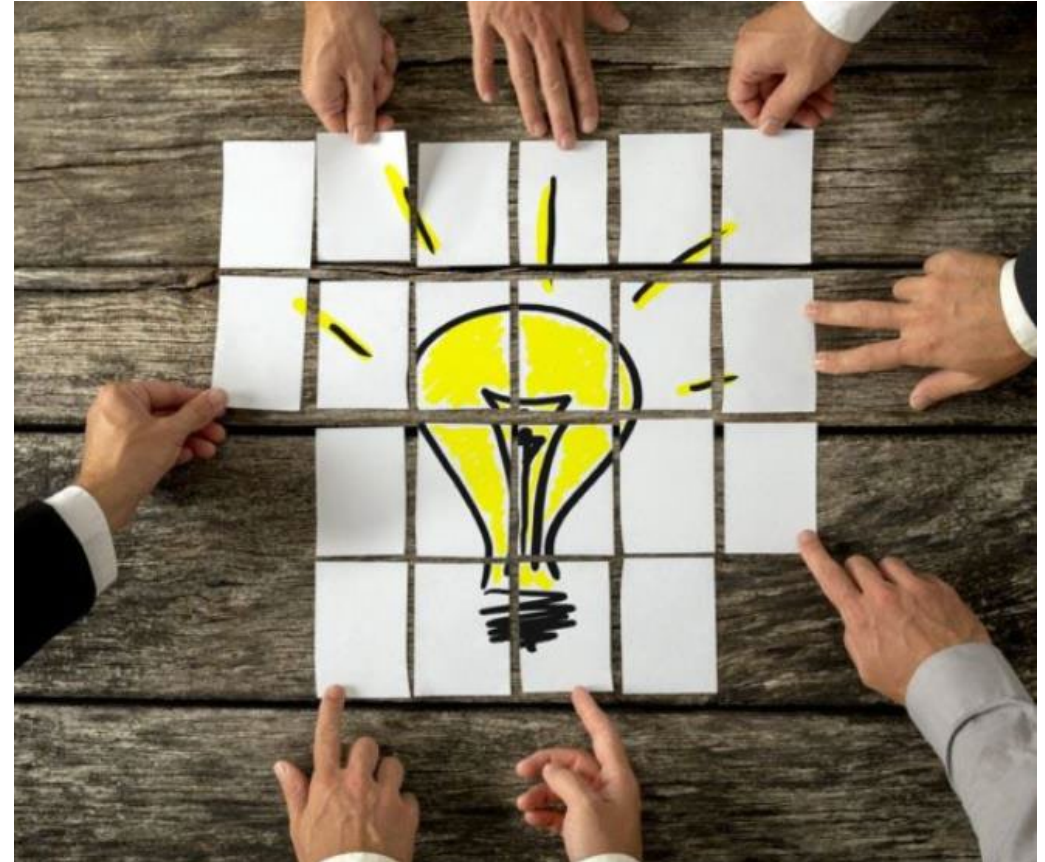
- Scientific advice from >1 NCA in a single procedure
- Facilitate multinational clinical trials, MRP/DCP

Examples of supports for innovation at national level



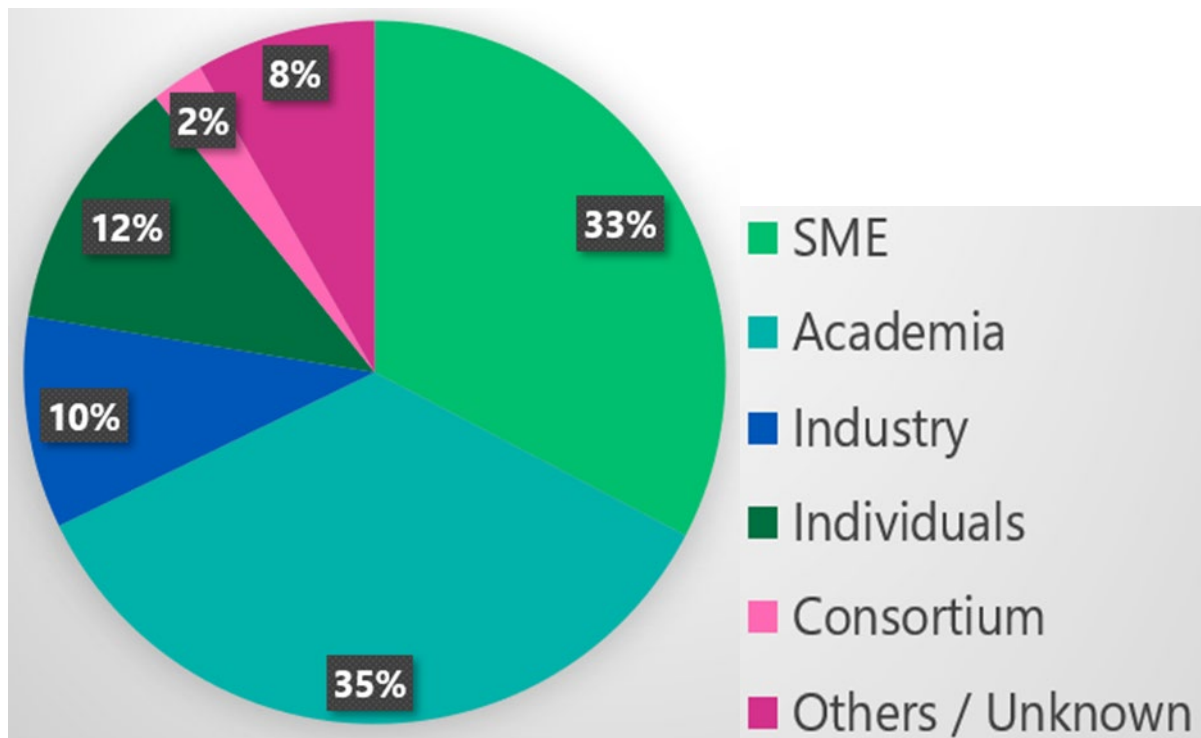
National Innovation offices

- An initial point of contact for innovators
- Opportunity to raise general queries relating to innovative products and technologies
- Contact can be made at any stage of development but early interaction encouraged
- Innovation offices can signpost and provide information on relevant supports at national and European level

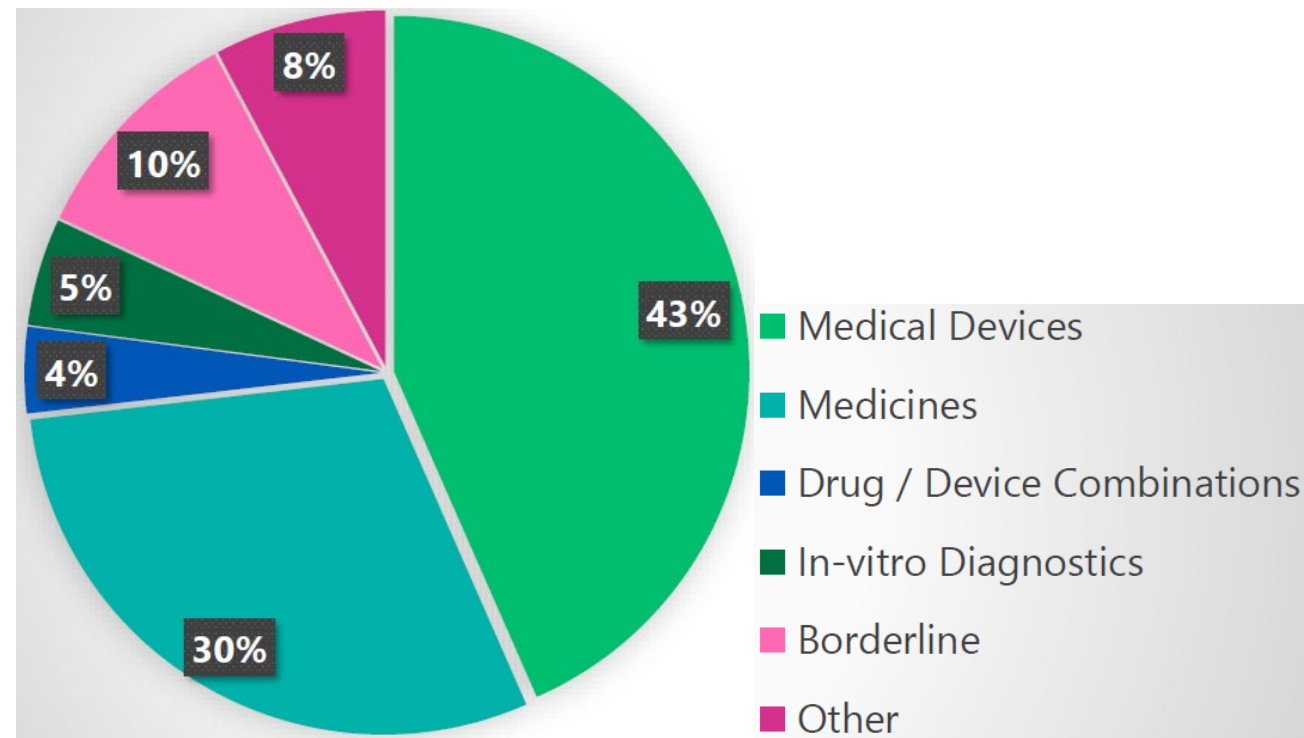


Innovation Office Queries

Origin of HPRA Innovation Office queries

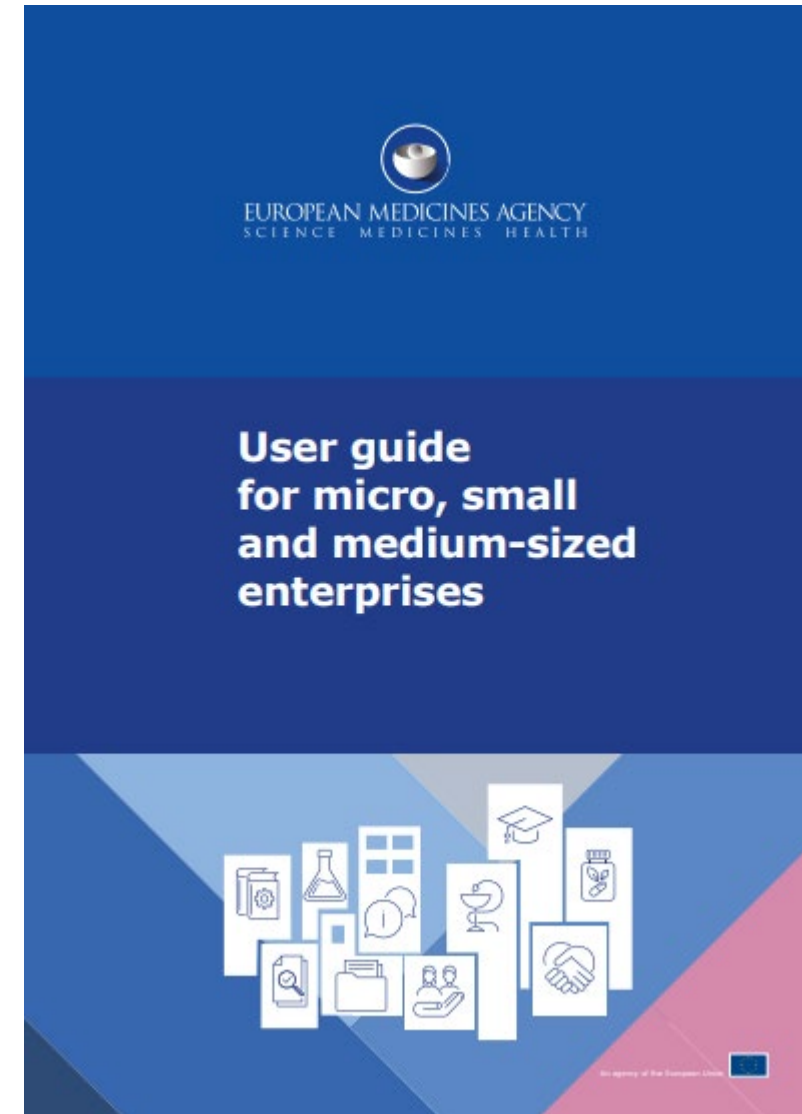


HPRA Innovation Office queries – product type



National provisions for SMEs

- Annex of the EMA's SME user guide provides information on national provisions for SMEs including contact points
- Contact points or national innovation offices can provide further details



Mutual benefits from engagement

- Support the dynamic innovative environment within the EU
- Clarify regulatory requirements at an early stage and help to avoid issues at later stages of development
- Encourage developers to make optimal use of available regulatory supports and inform the future development of those supports
- Ultimately help to provide safe and timely access to innovative medicines



Thank you

