European Medicines Agency
Support to SMEs

Tuesday 12 November 2019 09:00 - 10:30
EU financial support R&D through Horizon 2020 and EMA’s support to SMEs

Bio-Europe 2019, Hamburg, Germany

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Stakeholders and Communication Division
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The presenter does not have any conflict of interests.
SMEs: an important source of innovation

EU SME regulation(EC) No 2049/2005 of 15 December 2005

Aims to promote innovation and development of new medicines for human and veterinary use by SMEs

A single interface

“One-stop-shop”

Assistance to SMEs

Regulatory, administrative and procedural support.

Fee incentives

Regulatory procedures e.g. scientific advice,

Facilitates communication

With SMEs in veterinary and human pharma sector.

Coordinating & networking

Working closely with EU bodies.
Registered SMEs

- From 28 EU countries
- Size: 40% micro, 35% small, 25% medium-sized
- 78% human, 4% vet, 4% human/vet, 14% service providers
- 47% are development stage companies
- 22% developing or marketing generics
- 23% developing or marketing orphan medicines
- 11% developing or marketing paediatrics medicines
- 7% developing advanced therapies (ATMPs)
Regulatory, administrative and procedural assistance
Regulatory assistance

Examples of topics

- SME definition, SME incentives and translation assistance
- Scientific advice, orphan designation: guidance on procedure and timelines
- Regulatory aspects e.g. data protection and market protection, legal basis for submission of dossier, market exclusivity (orphan), eligibility to the centralised procedure, conditional and exceptional circumstances marketing authorisation
- PRIME e.g. how to apply, when to apply and eligibility
- Pediatric requirements
- Packaging and labelling requirements
- Clinical trials requirements
- Eudravigilance registration, Pharmacovigilance fees
- Questions on Horizon 2020 Funding, IMI
Scientific Advice

- Scientific Advice and f/u requests
- Protocol Assistance and f/u requests

<table>
<thead>
<tr>
<th>Year</th>
<th>Scientific Advice</th>
<th>Protocol Assistance</th>
<th>Total</th>
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<td>2018</td>
<td>466</td>
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- 45% by SMEs
- 31% by SMEs
Scientific Advice

- Scientific advice can be provided on ANY scientific question – quality, non-clinical and clinical
- At any time point of the development – early advice with subsequent follow-up is recommended
- Advice on eligibility of the proposed development for Conditional approval/Exceptional circumstances
- Protocol assistance for designated orphan medicinal products
- Qualification of biomarkers and other novel methodologies
- Parallel Scientific Advice with HTA bodies
- Parallel Scientific Advice with FDA
Take home messages

1. Engage with regulatory authorities
2. Seek regulatory and scientific advice early
3. Discuss pre- and post-licensing evidence generation plans for approval and access.
Thank you for your attention

Any questions?

Further information

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