European Medicines Agency
Support to SMEs

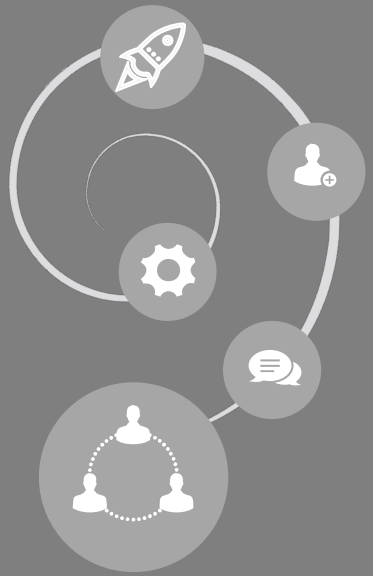
Tuesday 12 November 2019 09:00 - 10:30
EU financial support R&D through Horizon 2020 and EMA's support to SMEs

Bio-Europe 2019, Hamburg, Germany

Presented by Constantinos Ziogas
Stakeholders and Communication Division

Disclaimer

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,

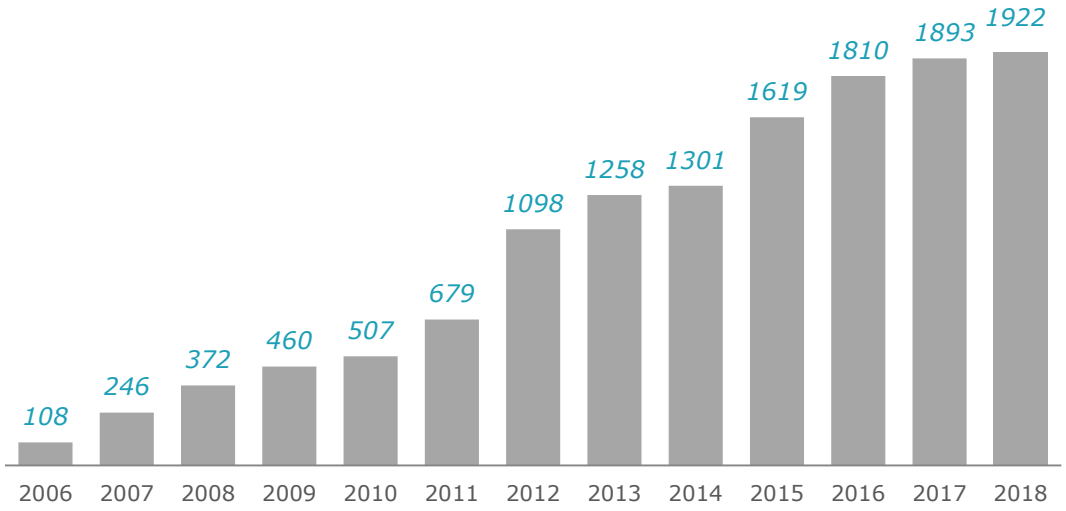
Facilitates communication

With SMEs in veterinary and human pharma sector.

Coordinating & networking

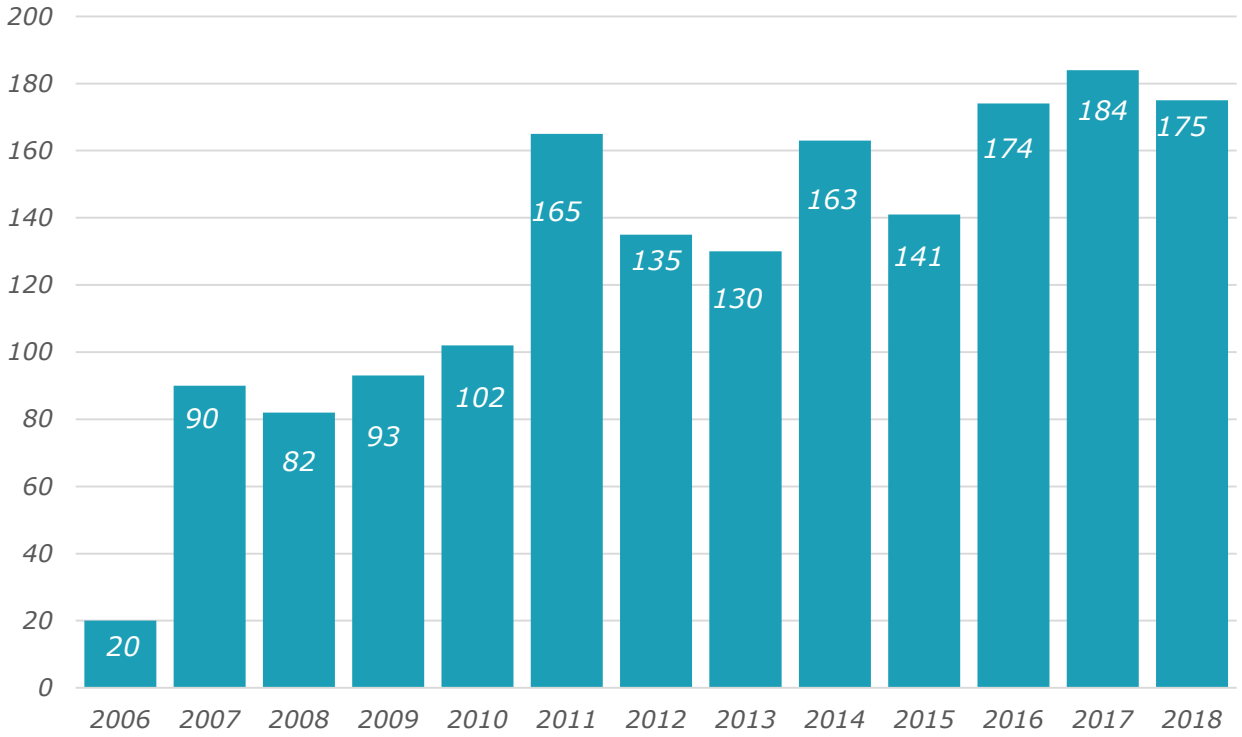
Working closely with EU bodies.

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)*

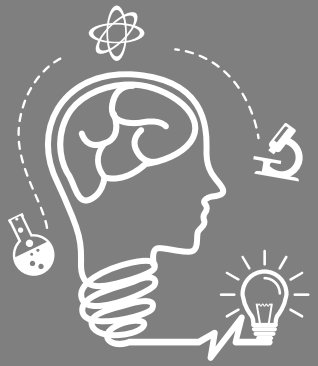
Regulatory, administrative and procedural assistance

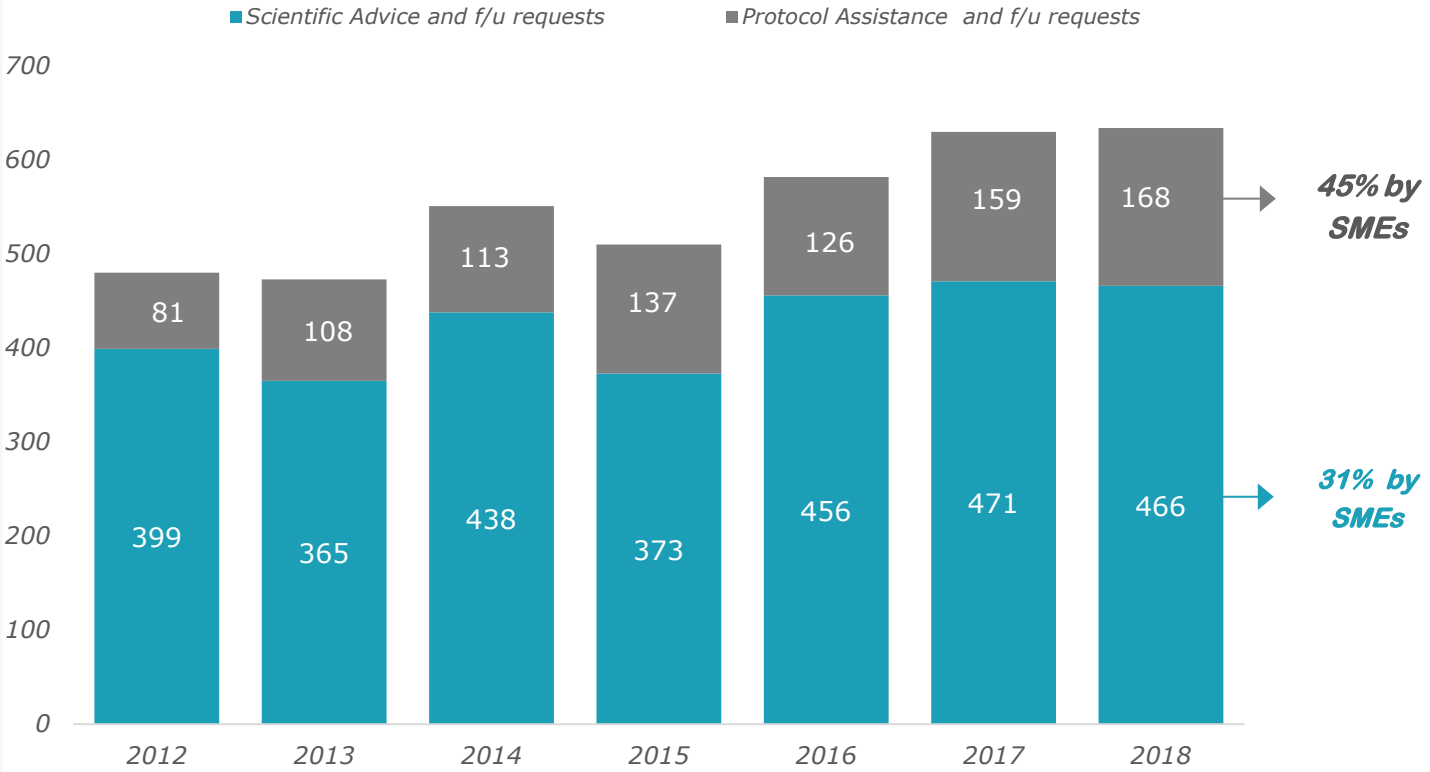


Regulatory assistance *Examples of topics*

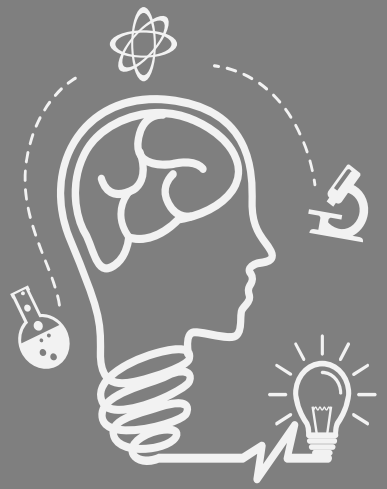
- SME definition, SME incentives and translation assistance
- Scientific advice, orphan designation: guidance on procedure and timelines
- Regulatory aspects e.g. data protection and market protection, legal basis for submission of dossier, market exclusivity (orphan), eligibility to the centralised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

Scientific Advice





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

constantinos.ziogas@ema.europa.eu

Temporary visiting address Spark building • Orlyplein 24 • 1043 DP Amsterdam • The Netherlands
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Send us a question via www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000

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