European strategy for SMEs in the pharmaceutical legislation

European Medicines Agency roundtable with stakeholders on the 10-year anniversary of the SME Office
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Agenda

- **Background**
- In the pipeline
- Conclusions

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Background

Main legal instruments:

- Art. 70 of Reg. (EC) No 726/2004 requesting to adopt **reduced fees**, **deferral of fees** and administrative assistance to SMEs

- EC Reg. (EC) No 2049/2005 setting up the rules for the **payment of fees** to and the receipt of **administrative assistance from EMA** by SMEs

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Background

Objectives:

- Promote innovation and the development of new medicines
- Reduce the costs of SMEs for the marketing authorisation (MA) procedures
- Avoid weakening the financial situation of SME during the assessment of the MA

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Background

Measures put in place for **human** and **veterinary** medicines:

- Deferral of fees
- Conditional fee exemption
- Fee reductions
- **'SME office' at EMA**
- Translation provided by EMA
- User guide

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Background

Fee reductions (examples)

- 90% reduction to the inspection fee,
- 90% reduction for scientific advice and free of charge for scientific advice for orphans,
- 90% reduction to the maximum residue limits fees

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Background

Administrative assistance from the **''SME office' (examples)**

- advice to applicants
- facilitate communication
- workshops and training sessions for applicants

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Background

Other legal instruments

- New Reg. (EU) No 658/2014 on **fees** payable to the European Medicines Agency for the conduct of **pharmacovigilance activities** in respect of medicinal products for human use

Incentives

- Fee reduction for SME (60% of the applicable amount for post-autorisation safety studies)
- Fee exemption for micro entreprises

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Background

Other instruments:

- Reg No 1394/2007 on **advanced therapy medicinal products**
  - **Incentive**
  - Certification quality and non-clinical data for advance therapies developed by SMEs
- **Impact assessment** for any new legislative proposal - with an assessment of impact on SMEs

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In the pipeline

Legal instrument

- Proposal for a Regulation of the European Parliament and of the Council on **veterinary medicinal products**

Proposal from the EC

- *"In order to help small and medium-sized enterprises to comply with the requirements of this Regulation,* ***Member States shall establish national helpdesks."***

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In the pipeline

Commission Expert group

- **STAMP - Safe and timely access to medicines for patients**

Aim

- Optimise the use of current regulatory tools which will benefit innovation for all including SMEs e.g. conditional marketing authorisation, adaptive pathways pilot project, PRIME (regulatory support and accelerated assessment for innovative medicines of major interest for public health- Earlier entry into the scheme at the proof-of-principle phase for SMEs)"

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Conclusions

- Help small, dynamic players
- Increase the knowledge of the regulatory environment
- Tailor-made provisions
- Contribute to innovation

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Thank you for your attention

More information

http://ec.europa.eu/health/human-use/index_en.htm

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